

Regulatory Reform in the United States

**Government Capacity to Assure High Quality
Regulation**



ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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FOREWORD

Regulatory reform has emerged as an important policy area in OECD and non-OECD countries. For regulatory reforms to be beneficial, the regulatory regimes need to be transparent, coherent, and comprehensive, spanning from establishing the appropriate institutional framework to liberalising network industries, advocating and enforcing competition policy and law and opening external and internal markets to trade and investment.

This report on *Government Capacity to Assure High Quality Regulation* analyses the institutional set-up and use of policy instruments in the United States. It also includes the country-specific policy recommendations developed by the OECD during the review process.

The report was prepared for *The OECD Review of Regulatory Reform in the United States* published in 1999. The Review is one of a series of country reports carried out under the OECD's Regulatory Reform Programme, in response to the 1997 mandate by OECD Ministers.

Since then, the OECD has assessed regulatory policies in 16 member countries as part of its Regulatory Reform programme. The Programme aims at assisting governments to improve regulatory quality — that is, to reform regulations to foster competition, innovation, economic growth and important social objectives. It assesses country's progresses relative to the principles endorsed by member countries in the 1997 *OECD Report on Regulatory Reform*.

The country reviews follow a multi-disciplinary approach and focus on the government's capacity to manage regulatory reform, on competition policy and enforcement, on market openness, on specific sectors such as telecommunications, and on the domestic macro-economic context.

This report was prepared by Scott Jacobs, and Rex Deighton-Smith in the Public Management Service of the OECD. It benefited from extensive comments provided by colleagues throughout the OECD Secretariat, as well as close consultations with a wide range of government officials, parliamentarians, business and trade union representatives, consumer groups, and academic experts in the United States. The report was peer-reviewed by the 30 member countries of the OECD. It is published under the authority of the OECD Secretary-General.

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1. Aggregate number of hours spent filling out federal government forms

Executive Summary

Background Report on Government Capacity to Assure High Quality Regulation

Can the national administration ensure that social and economic regulations are based on core principles of good regulation? Regulatory reform requires clear policies and the administrative machinery to carry them out, backed up by concrete political support. Good regulatory practices must be built into the administration itself if the public sector is to use regulation to carry out public policies efficiently and effectively. Such practices include administrative capacities to judge when and how to regulate in a highly complex world, transparency, flexibility, policy co-ordination, understanding of markets, and responsiveness to changing conditions.

Regulatory reform was pioneered in the United States and initiatives to improve the quality of national regulation have been underway for 25 years. They have been promoted mainly by the President, though recently the Congress has been more active. The most important general trend is the enormous shift since the 1970s away from anti-competitive economic regulation toward social regulation, which has greatly improved the benefits of the regulatory system as a whole, since social regulations are much more likely to produce net benefits than do economic regulations.

By many measures, the capacities of the US federal government for assuring the quality of federal regulation are among the best in OECD countries. Considerable investments in the institutional, policy, and legal infrastructure for quality regulation has produced well-functioning systems in the critical areas of forward planning, regulatory impact analysis, centralised quality control, and consultation with affected entities. The public debate is intensive and well-informed, and includes input from academia and think-tanks which provide innovative ideas and critical analysis of efforts and progress. Annual reports from the Executive Office of the President reporting on the costs and benefits of federal regulation are a valuable contribution to reform efforts, and are unique among OECD countries.

But the US regulatory system continues to have problems with both cost and policy effectiveness. Studies from different sources suggest that net social benefits for social regulations issued in recent years are positive, a significant though not a robust finding, but that many individual regulations impose costs higher than benefits. This means that aggregate costs of regulations – credibly estimated at between 4 and 10 per cent of GDP — could be substantially reduced without reducing social welfare. US regulatory habits of excessive detail, legalism, and rigidity are still dominant. At the heart of the most severe federal regulatory problems is the poor quality of primary legislation, which limits, and threatens to reverse, the benefits to be gained from regulatory reform. These problems are exacerbated by the inconsistencies, uncertainties, and complexities arising from the state/federal interface, which sometimes reduces accountability for regulatory decisions.

A series of improvements relating to performance measures, more intensive impact analysis, and congressional oversight has been launched in recent years, but there is as yet no assessment of their effects on regulatory quality and no comprehensive view of how these reforms fit together.

A more structured process of rolling reviews of primary legislation could contribute to correcting some of these problems. Continuing efforts are needed to improve the responsiveness of the regulatory system. Substantial gains could be won by rationalising the proliferation of regulatory quality controls; reviewing policy areas rather than individual rules; and experimenting with use of advisory bodies for the reviews. Mandatory regulatory quality controls should be expanded to cover economic regulation. Operational guidance on use of alternative policy instruments could encourage regulators to be more innovative. Finally, co-ordination with the states on regulatory reform could preserve and extend the benefits of regulatory reform at the national level.

1. THE INSTITUTIONAL FRAMEWORK FOR REGULATORY REFORM IN THE UNITED STATES

1.1. *The administrative and legal environment in the United States*

Like other OECD countries, the United States has over the course of a century constructed an enormous and complex regulatory state to provide citizens a wide range of vital services and protections, ranging from accessible buildings to safe food to a cleaner environment. In addition to new laws, over 60 executive agencies in the federal government are authorised to issue subordinate regulations. Each year, they issue between 4 000 and 5 000 new regulations. More than 200 volumes of federal rules are now on the shelves, and credible estimates of their direct costs as well as the value of their benefits for citizens and enterprises range from 4 to 10 per cent of GDP.¹ The result is that “federal regulations now affect virtually all individuals, businesses, State, local and tribal governments, and other organisations in virtually every aspect of their lives or operations.”²

The role of regulation in American governance is at the centre of an intensive decades-long debate involving *ideological* issues of the role of the State in society; *economic* issues of the role of regulation in a dynamic and innovative economy integrating into world markets; *social* issues of the services and protections that should be provided by the State to its citizens; *federalist* issues of the balance between federal powers and state rights; *institutional* issues rooted in the constant struggle between the powers of the Congress, the President and the Executive Branch and the judiciary; and *constitutional* issues such as individual property rights versus collective rights.

Box 1. Good practices for improving the capacities of national administrations to assure high-quality regulation

The OECD Report on Regulatory Reform, which was welcomed by ministers in May 1997, includes a co-ordinated set of strategies for improving regulatory quality, many of which were based on the 1995 Recommendation of the OECD Council on Improving the Quality of Government Regulation. These form the basis of the analysis undertaken in this report, and are reproduced below:

A. BUILDING A REGULATORY MANAGEMENT SYSTEM

1. Adopt regulatory reform policy at the highest political levels.
2. Establish explicit standards for regulatory quality and principles of regulatory decision-making.
3. Build regulatory management capacities.

B. IMPROVING THE QUALITY OF NEW REGULATIONS

1. Assess regulatory impacts.
2. Consult systematically with affected interests.
3. Use alternatives to regulation.
4. Improve regulatory co-ordination.

C. UPGRADING THE QUALITY OF EXISTING REGULATIONS

(In addition to the strategies listed above)

1. Review and update existing regulations
2. Reduce red tape and government formalities

Each President since Nixon has vowed to control the costs of the expanding federal regulatory state and to carry out policies more cost-effectively, while at the same time supporting the establishment of major new regulatory programmes. The balance of federal action has shifted from “regulatory relief” under Reagan to the Clinton philosophy of “regulatory quality” based on the idea that “The American people deserve a regulatory system that works for them, not against them.”³ Fuelling the debate is a veritable industry of regulatory reform analysis produced by think tanks and academia, by well-funded and energetic interest groups, and by Congressional, Presidential, and state offices. As in other OECD countries, much of the debate in the United States has centred about the economic costs of providing social benefits, and the difficulty of balancing the two.

The intensity and visibility of the debate on regulation is characteristic of policy-making in the United States. As in any country, the legal and administrative culture reflects the values implicit in the organisation of state, market, and society. In the United States, the nature and concept of regulation have been shaped by many values, key among them being traditional concerns for property rights and the rights of the individual (increasingly including rights to be free of externalities imposed by others); positive views of competition as consistent with individual self-reliance and risk-taking;⁴ and a preference for universal and specific processes and rules that bind everyone “fairly” (including the government). The tensions among these values explain much of the current debate on regulatory reform.

In many ways, the administrative and legal culture shaping regulation in the United States is the converse of that found in corporatist countries, where decisions are traditionally consensual and the administration has wide discretion in application, often sharing powers with organised market interests. Administrative action in the United States is taken within a strongly legalistic and adversarial environment based on open and transparent decision-making, on strict separation between public and private action, and on competitive neutrality between market actors. There are opportunities for anyone with an interest to challenge regulatory decisions before the courts on procedural and substantive grounds, which in theory enables regulated citizens to challenge and hold accountable the regulatory powers of the government, but also can reduce regulatory innovation and responsiveness.

These styles of the US regulatory system, in particular its aversion to competition controls as an instrument of social policy, have helped create the regulatory framework for one of the most entrepreneurial and dynamic economies in the world, while establishing high levels of protection for consumers, workers, and the environment. The highly open, pluralist, and participative rulemaking process — in which multiple interest groups compete at every stage to have their concerns heard and reflected in the outcome — is seen as essential to legitimacy (by avoiding “capture” by special interests) and to informed decision-making.⁵

Yet legalistic and adversarial styles have also produced what comparative studies of the American system find are more complex, detailed and inflexible regulations than those in other OECD countries. This undermines the results and raises the cost of policies.⁶ Experts have noted that “many of the laws Congress has passed call for highly prescriptive and often excessively costly regulation.”⁷ Superfund regulations on cleaning up toxic waste sites and corporate average fuel economy standards for cars are often cited as examples of regulations where costs vastly exceed benefits. A recent book warning against US regulatory complexity noted that “modern regulatory law resembles central planning,” and identified the cause as an extreme result of the American distrust of government discretion.⁸ Calling for a return to “common sense”, the book became a national best seller. A study of nursing home regulation reported that the United States had adopted over 500 federal nursing home standards, supplemented by state standards that doubled or tripled the volume of regulation. Australia had adopted only 31 broad results-oriented standards. Yet it was the Australian standards that produced the best results and best compliance, and by a very wide margin. The pursuit of reliability in US regulations produced so much

complexity and detail that they reduced the performance of the whole. A vicious cycle was seen: disappointment with regulatory performance produced demands to “tighten up” standards, which further worsened the problem of complexity and rigidity.⁹

The regulatory process has become so encumbered that the term “ossification” has been used.¹⁰ Procedures and relations with regulated entities tend to be highly formalised. One inquiry found a federal agency that needed an 18-foot chart, with 373 boxes, to explain its rulemaking process, and “this process was not unusually complex.”¹¹ Producing new regulations or revising old ones often requires several years. A regulation to reduce worker exposures to methylene chloride, a toxic chemical, required 12 years from beginning to finish. Such procedural complexity extends through the entire regulatory system, from development to judicial review to application.

There is considerable interest in the costs and benefits of federal regulation in the United States, though as in other OECD countries the costs of regulation continue to receive less attention than the costs of direct government spending. Several studies carried out in recent years suggest that federal regulation costs several hundred billion dollars annually, and may produce even greater benefits. Most recently, the Office of Management and Budget (OMB) in the Executive Office of the President reported to Congress that federal regulations related to the environment, safety, and health cost between \$170 billion to \$230 billion per year, and produce between \$260 billion to \$3.5 trillion in annual benefits (the huge range in benefits estimates is largely due to uncertainties about the impacts of the Clean Air Act).¹² Economic controls on entry and prices cost around \$70 billion per year, while producing few benefits. Hence, these kinds of regulations probably reduce social welfare. In addition, the annual costs of federal paperwork for citizens and businesses have been estimated by Hopkins at around \$230 billion, though these figures are contested by OMB, include tax compliance costs, and may overlap with other estimates.¹³ As noted, the total direct costs of regulation and paperwork appear to be between 4 and 10 per cent of GDP, while the total benefits are uncertain. The costs and benefits trend upward or downward is also uncertain, though OMB estimated in 1997 that regulatory costs as a percentage of GDP had stayed about the same since 1988.¹⁴

These studies recognise that such benefit and cost estimates are very uncertain due to what OMB calls “enormous data gaps” and “a variety of estimation problems.” The direct costs are significant understatements of the full costs of regulations, because they miss impacts on productivity, welfare, and dynamic effects such as lost opportunities to create wealth.¹⁵ Indirect beneficial effects that result from better health and longer lives are not included either. There are significant methodological problems; for example, the estimates mix different data sources.¹⁶ Yet these estimates are a large advance in understanding the costs and benefits of regulatory activities, and work is underway in OMB and elsewhere to improve them. Unfortunately, these aggregate cost estimates cannot be compared with those of other OECD countries due to an almost total lack of such data outside of the United States.

These kinds of global estimates are not very useful, however, in assessing whether particular regulations are beneficial, nor whether the regulatory costs maximise net benefits. In both cases, data at the micro-level suggest that the opportunities for improving the cost-effectiveness of federal regulation are very large. Research on 106 regulations suggests that just two federal rules (automatic restraints in cars and lead reductions in gasoline) produced over 70 per cent of total net regulatory benefits, and that more than half of the federal government’s regulations fail a strict benefit-cost test, using the government’s own estimates.¹⁷ Studies have repeatedly shown that redirecting regulatory activities away from low-priority to high-priority issues would have enormous payoffs in terms of delivering benefits to citizens at lower cost. For example, safety and health regulations aimed at reducing fatality risks have saved lives at costs ranging from \$10 000 to \$72 billion per life saved.¹⁸ A recent study found that if existing regulations were re-targeted at those health and safety risks where lives could be saved at lowest cost, some 60 000 more deaths could be avoided each year without increasing regulatory costs.¹⁹

Legislative branch. All regulation starts in an act of Congress that defines the goals of regulatory programmes, identifies the agency responsible for achieving them, and contains substantive and procedural requirements as to how the agency will work.²⁰ Hence, the quality of law is a crucial issue for regulatory quality at all levels. Delegations of regulatory authority to the public administration vary widely. In some cases, laws are so specific that they require no subordinate regulations. In other cases, laws are so broad and general that subordinate regulations determine their impacts. In these cases, federal regulatory agencies have wide substantive discretion on when, what and how to regulate. A trend is underway, however, toward more detailed laws that circumscribe administrative discretion. This trend is rooted in Congressional frustrations about the performance of regulatory agencies and the continual tussle between the Congress and the President for control over policy. It has given rise to concerns that the Congress is “micro-managing” regulatory decisions, particularly in environmental protection, in ways inconsistent with good regulatory decisions and innovation. Congressional oversight after regulations are developed is also quickly increasing. Since 1996, final regulations are sent to the Congress for review (though the Congress has not yet exercised its authority to block any of these regulations), and since 1998 regulators are required to set performance standards for their actions.

Executive Branch. The President has constitutional authority to oversee the activities of the executive branch, but the wide range of designs in regulatory bodies varies the extent to which he can control their actions. In general, federal regulatory bodies are organised in two ways: as executive departments and agencies directly accountable to the president (which include most of the social regulatory agencies) or as independent commissions (a model begun in 1887 with the Interstate Commerce Commission) whose officers are appointed by the president, with the consent of the Senate, but whose terms are fixed by law (which include most of the economic regulatory agencies). The heads of some regulatory agencies are Cabinet officers; others are not.

Judiciary. No discussion of US regulation would be complete without acknowledging the role that the courts play in regulatory decisions. Issues that other countries would resolve through management and dialogue are resolved in the United States by the courts. “The courts have played a profoundly important role in setting the limits of congressional, presidential, and even judicial influence over regulatory policy-making in the agencies...the courts are empowered to hear variety of challenges to regulatory decisions, ranging from the delegation of authority to agencies by Congress to the legality and fairness of agency dealings with individual regulated parties.”²¹ Legal challenges are the norm rather than the exception. In the environmental area, almost every major regulation is challenged in court. The workings of the common law system led to the emergence of a single judge as the *de facto* regulator of the huge telecommunications industry. An assessment of the impact of the courts on regulatory quality is beyond the scope of this review, but it is fiercely debated. For example, since successful legal challenges can be based on the poor quality of information and analysis, judicial review may have promoted the use of empirical analysis by regulators. But since judicial review increases uncertainties and delay in regulatory policies, it may also have undermined the responsiveness and transparency of the regulatory system.

The States. Finally, regulation in the United States is a complex mixture of federal, state, and local rules and enforcement responsibilities. The 50 state governments have legal and regulatory authority in their areas of competence, including all areas not expressly pre-empted by federal legislation, and may delegate legal and regulatory authority to regional, local, or municipal governments. Interactions between federal and state regulatory powers are in constant flux, with concentration in some policy areas and decentralisation in others. The states are often seen as laboratories for regulatory innovation and experimentation, but, as in other federal governments, however, the United States has experienced a dramatic and increasing centralisation of regulatory power toward the federal level.²² Many of the concerns heard about regulation in the United States focus on the complexity, coherence, and lack of accountability resulting from the interaction of federal and state regulations.

Box 2. **Milestones in improving the quality of social regulation in the United States**

- 1971** Quality of Life Review is undertaken as a means of improving regulatory co-ordination.
- 1974** Inflation Impact Statements are prepared for major regulations by the Council on Wage and Price Stability
- 1978** Economic Impact Analysis is conducted by regulatory agencies and CWPS.
- 1980** Office of Information and Regulatory Affairs (OIRA) is established by the *Paperwork Reduction Act* to provide centralised paperwork review and information management.
- Regulatory Flexibility Act* requires agencies to assess the impact of regulations on small entities and publish regulatory activities in annual Agenda of Federal Regulations.
- 1981** Presidential Taskforce on Regulatory Relief is established (a Cabinet level regulatory policy group, chaired by the Vice President). OIRA is charged with responsibility for formal regulatory review (policy and analytical oversight) by executive order of most federal regulations at proposed and final stages.
- Regulatory Impact Analysis* (including mandatory benefit-cost analysis) is mandated by executive order.
- 1985** Regulatory planning process is established, including publication of annual Regulatory Program of the US Government, containing descriptions of about 500 “significant” regulations under development.
- 1989** Council on Competitiveness (Cabinet level regulatory policy group chaired by Vice President) is established.
- 1993** Regulatory review by OIRA (with new time limits) and benefit-cost analysis are reaffirmed by President Clinton; the Regulatory Working Group is established to advise the Vice-President. Council on Competitiveness is disbanded.
- National Performance Review* is established under the Vice President to “reinvent” government on results-oriented principles. Regulators are ordered to work co-operatively with the regulated community to find the best regulatory solutions.
- Government Performance and Results Act* requires government departments to prepare for Congress strategic plans that identify, among other issues, a mission statement, strategic goals and objectives, strategies to achieve goals, programme evaluations, major management problems, and data capacity.
- 1995** Executive order requires all regulators to conduct a comprehensive review of regulations, with the aim of eliminating 16 000 pages of regulations from the 140 000 pages in the Code of Federal regulations.
- Unfunded Mandates Reform Act* provides the first statutory basis for government-wide RIA; regulators are required to assess expected costs and benefits for most important regulations (but the benefit-cost principle is not included); the federal government must find financing if costs fall on state, local, or tribal governments.
- Amended Paperwork Reduction Act* widens OMB authority and requires OIRA to establish government wide and agency specific paperwork reduction goals.
- 1996** *Small Business Regulatory Enforcement Fairness Act* toughens requirements to consider small business impacts of regulations.
- Congressional Review Act* requires regulators to send all regulations to the Congress for review; most important rules have a delay of 60 days before becoming effective. Congress may nullify all rules within 60 days.
- 1997-8** *Treasury and Government Appropriations Act* requires OMB to submit to Congress estimates of total annual costs and benefits of federal regulations, and recommendations for improvements.

The effect of this complex environment on the quality of the national regulatory system is one of the key questions facing the United States. The great challenge of regulatory management and reform in the federal government has been construction of government-wide quality principles and processes of regulatory quality control. This requires both “discipline and flexibility” in the reform programme to accommodate such variety.²³ Even this goal has been contested. Development of regulatory quality controls in the federal government has been characterised, to a degree unusual among OECD countries, by tension between, on one hand, the need for clearer political accountability and strong management of a large and fragmented regulatory system, and, on the other hand, the desire that individual regulatory decisions should be free from political influence (which dates from the anti-corruption “good government” movement of the 1920s).

1.2. Recent regulatory reform initiatives to improve public administration capacities

The focus of reform shifted in the 1980s from economic deregulation to fast-growing social regulation. Today, the United States is rare among OECD countries in focusing on improving the quality of social regulations (defined as meeting benefit-cost and cost-effectiveness tests, while reaching defined policy goals) and reducing paperwork burdens as the main objectives of regulatory reform. This is consistent with the fact that estimates of the costs of federal regulation suggest that social regulations impose costs 3 to 4 times higher than do economic regulations, though this report concludes that economic regulations have been neglected in the current reform programme.²⁴

For the Congress and the Executive, the 1990s have been an active period for regulatory reform (see Box 2 for milestones). A series of important improvements to performance measures, impact analysis, and congressional oversight has been launched and is in the implementation stage. These reforms hold considerable promise for improving regulatory quality, but they have been piecemeal in nature, and there is no comprehensive view of how they fit together. Indeed, in some cases, they are narrow in objective, and not entirely consistent. Although these reforms have not yet worked their way through the system, a series of additional reforms are being debated in the Congress. While useful additional steps can be taken, it should also be recognised that a multi-year period of policy stability and determined implementation, combined with a thorough re-assessment of the long-term objectives of reform and how these various reform strategies support those objectives, is needed to allow the reforms to take hold.

In 1993, President Clinton issued an executive order (an instruction to the executive branch that in most cases does not establish legal rights) on “Regulatory Planning and Review” that aimed at “building the foundation for a regulatory system that will improve the lives of Americans without imposing undue costs and burdens.” Based on earlier orders issued by President Reagan, it mandates for regulators a programme of regulatory quality standards, rational decision procedures, development of consensual rather than adversarial approaches, promotion of innovative policy instruments, and centralised oversight by the Office of Management and Budget of the most important regulations.

In 1993, Vice President Al Gore launched a systemic view of institutional reform and the “culture” of the public administration under the National Performance Review (NPR). The NPR aims to “move from red tape to results to create a government that works better and costs less.” Under the goal of “eliminating regulatory overkill,” the Review recommended 10 regulatory reforms that are similar to best practices accepted by OECD countries, including:

- Encourage more innovative approaches to regulation.
- Encourage consensus-based rulemaking.

- Streamline agency rulemaking procedures.
- Rank risks and engage in “anticipatory” planning.
- Provide better training and incentives for regulators.

Although subject to considerable criticism, the NPR has promoted review activity, and five years on remains a potentially important reform mechanism in the administration.

Another tool with potentially profound impacts on regulation is the Government Performance and Results Act of 1993. This law requires government departments to prepare and submit to Congress strategic plans that identify, among other issues, a mission statement, strategic goals and objectives, strategies to achieve goals, programme evaluations, major management problems, and data capacity. The strategic plans are supplemented by government-wide and agency-specific annual performance plans, the first of which were required in February 1998. If it works as intended, the Results Act should stimulate regulatory reform by making regulatory failures more transparent and increasing accountability to the Congress. Its own performance in this respect is not yet demonstrated. Identifying results-oriented performance measures has been difficult, but in the 1999 budget requests, regulators have generated a series of quantitative measures of real importance (see Box 3).

Box 3. Selected 1999 performance measures proposed by regulatory agencies under the Government Performance and Results Act

Department of Labour

- Decrease fatalities in the construction industry by 3% by focusing on the four leading causes of fatalities (falls, struck-by, crushed-by, and electrocutions and electrical injuries).
- Increase compliance with fair labour standards laws and regulations by 5% in the San Francisco and New York City garment industries and poultry processing.

Food and Drug Administration

- Achieve adoption of the Food Code by 25 per cent of states.
- Assure that 40 per cent of domestic produce is grown and processed using good agricultural and manufacturing practice guidance for minimising microbial contamination.

Transportation Department

- Reduce the number of transportation-related fatalities to fewer than 44 407, even with a projected increase in the miles travelled.

The 104th Congress (1995-1996) debated a raft of legislation on regulatory reform. Significant laws emerging from the debates include the Unfunded Mandates Reform Act of 1995, the Paperwork Reduction Act of 1995 and the Small Business Regulatory Enforcement Fairness Act of 1996. These are discussed below.

Historical background. The current programme builds on 25 years of earlier efforts that saw the development of two very different reform trends: deregulation of economic controls, and establishment of quality standards and processes for new social regulations and federal paperwork.

Economic objectives with respect to price stability, competition, job creation, and trade have provided strong and consistent support for regulatory reform efforts. The economic recession and surge of inflation that began in 1974 made regulatory costs for the first time "a national preoccupation"²⁵, and President Nixon directed that major regulations be assessed for inflationary impact. In 1980, the Congress resolved that the president should implement a "Zero Net Inflation Impact" policy that would require existing regulations to be eliminated as new regulations were added.²⁶ This unrealistic resolution was soon forgotten.

Deregulation became central to economic policy in the mid-1970s as evidence grew that government intervention was needlessly restricting competition and harming the performance of many sectors. This led to deregulation in many areas: financial deregulation (abolition of fixed brokers' fees) began in 1975, followed by deregulation of the railroads (1976), air cargo (1977), airlines and natural gas (1978), satellite communications (1979), trucking, railroads again, financial institutions, cable television (1980), petroleum, radio (1981) and buses and communications equipment (1982). Replacement of price and entry controls with pro-competitive regulatory regimes, backed up by strong competition policies, continues today in many sectors (see Chapters 1, 3, 5, and 6 in Part I).

Attempts to impose quality controls on the use of delegated regulatory powers in social policy areas began in the 1970s "in reaction to the explosive growth of new regulatory programs" of the 1960s and 1970s.²⁷ By the mid 1970s, over 100 federal agencies were issuing economic and social regulations in areas such as health, safety, housing, agriculture, labour contracts and working conditions, environment, trade, and consumer protection. Their output was voluminous: the Code of Federal Regulations (the comprehensive collection of federal regulations) grew from 9 745 pages in 1950 to more than 100 000 pages by 1980 to almost 140 000 pages by 1995.

The new social regulations affected a far broader cross-section of economic, production and consumption activities than had older-style economic regulation, and hence they were far more visible and interactive. The administrative and economic side-effects of rapid regulatory expansion began, in the late 1960s, to command political attention. Conflict and duplication, for example, between various regulatory agencies occurred more and more frequently. Regulatory costs, both on and off-budget, escalated. The administrative on-budget costs of federal regulatory activities rose from \$4 billion in 1970 to over \$11 billion by 1994, while staffing of regulatory agencies rose from 70 000 to over 128 000 in the same period.²⁸

Through the 1980s, new data on aggregate direct and indirect regulatory costs drew increasing attention to the cumulative economic burden of social regulations. Other studies suggested that workplace and environmental regulation had had significant negative effects on productivity.²⁹ As information about such regulatory costs improved, regulation began to be viewed as a form of government spending that should be controlled as systematically as fiscal expenditures (regulatory budgeting is discussed in Box 8).

Criticism grew of the failure of detailed regulations to keep up with changing social, economic and technological conditions. By the 1980s, a political backlash against regulation had emerged, fuelled by the economic crisis of the time. The message was simple: "American life is burdened by too much regulation".³⁰ To federal officials, the problem was that existing control and oversight processes were not suited to regulations. "The response from the vast array of entities subject to the new forms of regulation created an urgent demand for greater co-ordination, rationality, and executive accountability in the regulatory process," wrote the Office of Management and Budget. New means were needed to manage the enlarged federal regulatory structure.

In 1981, President Reagan made "regulatory relief a top priority...one of the cornerstones of my economic recovery program." Agencies were directed to "weed out and eliminate wasteful, unnecessary, intrusive regulatory standards". Late in the 1980s, competitiveness in opening global markets became key to the regulatory reform program. "Domestic policies, including regulation, have to be considered in the much larger context of our ability to compete in an international economy," OMB stated in 1987. In 1989, regulatory reform was linked directly to US trade policy when President Bush established the cabinet-level Council on Competitiveness, chaired by the Vice-President, to review major regulatory issues. The Council was abolished by President Clinton in 1993 due to concerns about lack of transparency and bias toward business concerns.

2. DRIVERS OF REGULATORY REFORM: NATIONAL POLICIES AND INSTITUTIONS

2.1. *Regulatory reform policies and core principles*

The 1997 *OECD Report on Regulatory Reform* recommends that countries "adopt at the political level broad programmes of regulatory reform that establish clear objectives and frameworks for implementation."³¹ The 1995 *OECD Council Recommendation on Improving the Quality of Government Regulation* contains a set of best practice principles against which reform policies can be measured.³² The content of, and formal political commitment for, US regulatory reform policies demonstrates a high level of consistency with these recommendations.

The current reform policy for the executive branch establishes clear political accountability at the highest political levels. The framework reform policies are established directly by the President on the basis of his executive authority. In the Clinton executive order, the Vice President is identified as the principal advisor to the president on regulatory policy, planning and review, OMB (part of the White House office) as the "repository of expertise" on regulatory issues, and the head of the Office of Information and Regulatory Affairs (appointed by the president) as the co-ordinator of the policies. These administrative policies are backed up in some respects by laws supporting central review and impact analysis.

During the Clinton Administration, the National Performance Review has constituted another mechanism for regulatory reform. The NPR is conducted under the responsibility of the Vice-President, strengthening political commitment to reform and accountability at the highest levels.

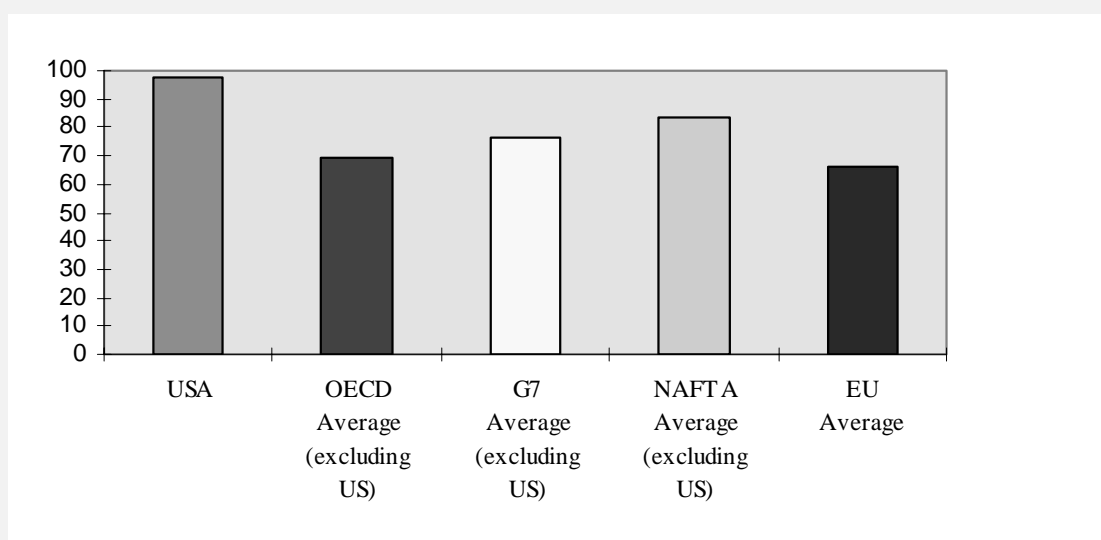
Consistent with the OECD recommendation that governments "establish principles of 'good regulation' to guide reform," explicit standards for regulatory quality have been adopted, as have principles of regulatory decision-making. Clinton's 1993 executive order is the primary reference for regulatory quality standards. The order requires that agencies take a "minimalist" approach to regulation, by promulgating "...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...."³³ It requires regulators to:

- Identify the problem to be addressed and assess its significance.
- Identify and assess alternatives to direct regulation, including economic incentives and information, and use performance standards to the extent possible if regulation is chosen.
- Set priorities by considering the degree and nature of risks from different sources.

- If regulation is the best method, design it in the most cost-effective way.
- Regulate only upon a reasoned determination that benefits justify costs.
- Base decisions on best, reasonably obtainable information on the need for and consequences of regulation.
- Avoid regulations that are inconsistent or duplicative with other regulations.
- Draft regulations to be simple and easy to understand.

Box 4. Indicators of policy commitment to regulatory reform in selected OECD countries³⁴

In this synthetic indicator of the formal commitment to and comprehensiveness of regulatory reform policies (based on self-assessment), the United States receives a very high score. This indicator looks at several broad aspects of reform policy, and ranks more highly those that cover all policy areas of regulation, that establish explicit standards for regulatory quality, and that are accountable to the highest political levels. The United States ranks among the highest among OECD countries on this indicator, indicating that much of the machinery of reform is in place. It must be noted, however, that the US regulatory quality policy does not cover independent regulatory commissions, a gap in the programme that is not picked up in this indicator.



Source: OECD Public Management Service.

These and similar principles in place since 1981 represent a critical shift in US regulatory culture: they reversed the burden of proof for regulation (by, for example, ordering that regulations not be issued unless regulators showed that benefits justified costs). Under this programme, regulators themselves must show why they should regulate, and demonstrate that regulation is the most beneficial feasible approach. In principle, uncertainty and lack of information work against rather than for regulation.

It is notable that the United States is one of only a handful of OECD countries to adopt a strict benefit-cost test for regulations. The OECD has recommended as a key principle that regulations should “produce benefits that justify costs, considering the distribution of effects across society.” Such a test is the preferred method for considering regulatory impacts because it aims to produce public policy that meets the criterion of being “socially optimal” (*i.e.*, maximising welfare).³⁵

Maximisation of social welfare, perhaps the broadest conceivable aim of reform, was placed alongside regulatory relief in 1981 as a major objective of regulatory reform. The 1981 executive order was the first to explicitly require that new regulations pass a social benefit-cost test and that regulatory objectives, not just individual rules, "be chosen to maximise the net benefits to society". The president, OMB said in 1991, seeks "a regulatory structure that appropriately balances the benefits and costs of Federal regulations for the country's long-term well-being...."

Although the economic concept of social welfare as articulated by OMB has always been quite broad, including both quantifiable and non-quantifiable benefits and costs, the benefit-cost test has drawn heavy criticism from those who believe that, in practice, quantified costs to businesses are given more weight than non-tangible social benefits. The Reagan Administration continued through the 1980s to emphasise regulatory "relief," a goal not always consistent with the principle of maximising social welfare. This had the effect of confusing the purpose of benefit-cost analysis and reducing its credibility.

In his 1993 order, President Clinton reaffirmed the importance of the benefit-cost test and stated that maximising social welfare is the aim of the regulation, but took care to recognise that "some costs and benefits are difficult to quantify" and that net benefits can include "potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity."³⁶

2.2. *Mechanisms to promote regulatory reform within the public administration*

Reform mechanisms with explicit responsibilities and authorities for managing and tracking reform inside the administration are needed to keep reform on schedule. As in all OECD countries, the United States emphasises the responsibility of individual heads of regulatory bodies for matters within their portfolios. Each regulatory body has responsibility for the implementation of its policies within the constraints of the applicable law and president's regulatory quality policy.

But it is often difficult for regulators to reform themselves, given countervailing pressures, and maintaining consistency and systematic approaches across the entire administration is necessary if reform is to be broad-based. Hence, to manage the large and complex US regulatory system, the United States has established a series of oversight mechanisms. Both the president and the Congress carry out strong regulatory oversight, the president through a central management office accountable directly to him, and the Congress through a system of oversight committees organised largely along program lines, and through investigations by its organs such as the General Accounting Office. The concerns of the two branches of government may not always coincide; a congressional committee, for example, may focus on implementation of a specific regulatory law, while the president may focus on the functioning of the regulatory system as a whole, consistency with empirical tests of benefit-cost and cost-effectiveness, and its consistency with his policies.

A long running theme of central management has been enhancing accountability for regulatory decision-making in a sprawling and fragmented regulatory system. Centralisation of review authority in the Office of the President is a means of exercising oversight on broad discretionary powers delegated to unelected officials. Semi-legislative delegation has been described as "counter to the basic democratic tenets" of the US system of government, requiring new forms of political oversight.³⁷ On practical grounds, the regulatory system seemed increasingly distant from elected officials: "...costly regulations... germinating and percolating through several Administrations, became creatures seemingly immune to political or policy influence, gaining and retaining a life of their own," complained OMB. Oversight of the regulatory system was placed in the Office of the President to enable the president to carry out his constitutional responsibilities as Chief Executive: "...because the President is accountable to the public –

the voter – for how his appointees execute the law, he is obligated to oversee and manage what they do."³⁸ The high priority placed on better regulatory analysis reflected a belief that regulators would not truly be accountable to the electorate unless the consequences – the social benefits and costs – of their actions were known.

Co-ordination between overlapping and inconsistent regulatory programs was an early objective of regulatory reform, and has continued to be an important stimulus, under both major political parties, for stronger central management. The first presidential initiative to improve regulatory management, a "Quality of Life Review", established in 1971 – was intended to improve interagency co-ordination in expansive areas of regulation. In 1978, interagency consultation and co-ordination were further strengthened, and executive orders on regulatory reform in 1981, 1985, and 1993 setting up and refining centralised regulatory oversight in OMB were intended in part to "minimise duplication and conflict" between regulations.

Co-ordination expanded over time from a focus on "consistent rules" to a wider focus on how to better balance competing values through the regulatory and political system. In 1986, the director of the White House Office of Management and Budget declared that "regulatory disarray" had resulted because "regulatory agencies, individually and collectively, did not appreciate the impact or the burden of what they were doing" and that "the regulatory system is desperately in need of a mechanism for balancing the demands of competing and conflicting regulatory agencies and programs."³⁹ Regulations, according to OMB, must fit into the larger legal, social, and economic context. The institution responsible for ensuring this was OMB itself.

In the executive branch, competition between president and Congress for influence over regulatory decisions had contributed to the emergence of an unusually centralised and hierarchical regulatory oversight process. The Office of Management and Budget within the Executive Office of the President has evolved to become among the most powerful of the central oversight bodies in any OECD country. This reflects the strong constitutional powers of the President in overseeing the executive branch.

The OMB has had a strong co-ordination, reviewing, and reporting role on regulatory reform since the earliest days of the policy. Located at the very centre of government, OMB is responsible for many central management tasks of government that have been very helpful to regulatory reform. These include preparation of the President's budget, legislative review, information policy, financial management, and procurement policy. The current staff of OMB in the responsible Office of Information and Regulatory Affairs (OIRA) number around 22, about half of its size 10 years ago.⁴⁰ The traditional government-wide authority of OMB and its control of many levers of influence in the public administration has given it the potential for enormous authority in promoting broad-based reform. This is an important lesson from the US experience.

A distinguishing characteristic of the Office of Information and Regulatory Affairs (OIRA) in OMB is its intimacy with every stage of regulatory decision-making in the agencies. President Reagan's 1981 order and subsequent orders have placed OMB firmly and unavoidably within the normal process of regulatory development. OIRA reviews the most important regulations three times: (1) at the planning stage during preparation of the annual Regulatory Plan; (2) at the proposed stage before they are published for comment in the Federal Register (the national gazette); and (3) at the final stage before publication as a finished rule. OIRA's role is to review the regulations and the impact analyses in order to identify decisions and policies that are not consistent with the president's policies, principles, and priorities; to co-ordinate among agencies; to discuss any inconsistencies with the regulators, and to suggest alternatives that would be consistent. OIRA is, in effect, the President's trusted intermediary in overseeing the regulatory apparatus of the federal government.

In addition, OIRA has legal authority under the Paperwork Reduction Act to review and nullify any “information collection” requirement imposed on citizens, businesses, or state and local governments. This far-reaching authority is described in more detail in Section 4.

Closeness to Presidential power is a two-edged sword. When OMB has the support of the President, it ranks among the most effective of regulatory reformers in the OECD area. Yet the President has other policy priorities as well as regulatory reform priorities, and OIRA has not always enjoyed consistent support. Criticisms of OIRA are often rooted in the ambiguous position of a body that claims to simultaneously represent a set of quality principles based on empirical decision-making, *and* the position of the President who must deal with political priorities and other possibly conflicting claims.

The growing role of OMB in the 1980s also raised concerns about fairness and accountability. During the Reagan administration, OMB regulatory review attracted considerable opposition on the grounds that the presidential supervisory program had “the potential to transgress substantive or procedural substantive limits”⁴¹ and that it intruded on the decision-making authority of the regulatory agencies. Critics charged that the review program was a “pervasive and persistent” effort “to shift the locus of discretionary decision-making authority from the agencies designated by the Congress to OMB.”⁴² Efforts to make the OMB review more transparent have laid to rest many of these concerns, and centralised presidential oversight of regulation has today become a permanent and routine element of the Washington policy-making apparatus.

The Small Business Administration has an increasing role, too, in reviewing assessments of small business impacts. The regulatory difficulties of small and medium-scale enterprises (SMEs) has been prominent since the early days of reform. The 1997 OECD Report on Regulatory Reform suggests that a priority reform issue in most OECD countries is reducing regulatory burdens on small and medium-scale businesses, which are disproportionately hit by administrative and other regulatory burdens to the extent that there are fixed compliance costs. The degree to which these are particular problems in the United States is not clear. Reports have found that SMEs in the United States are disproportionately affected by regulatory costs,⁴³ while a recent OECD report highlights the positive institutional framework existing in the United States, where a vibrant and diversified SME sector operates.⁴⁴ It is entirely possible, however, that both of these are true, and that a vibrant SME sector would perform even better if regulatory burdens were reduced. For these reasons, an important feature of the regulatory and paperwork reduction programmes in the United States has been the focus on SMEs.

The Congress enacted the Regulatory Flexibility Act (RFA) in 1980, and sixteen years later, the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) to correct flaws in the RFA that had undermined its effectiveness. The Small Business Administration’s (SBA) Office of Advocacy has been the main institution to monitor compliance with these laws. Both acts increased SBA powers in the federal regulatory process.

The most significant mechanism concerns the RFA review process which requires federal agencies to analyse the anticipated effects of proposed rules on small entities unless they certify that the rules will not have a “significant economic impact on a substantial number of small entities”.⁴⁵ Agencies are also required to identify alternative regulatory approaches. This review is done through a “Regulatory Flexibility Analysis” and notification in the *Federal Register*.⁴⁶ SBREFA reinforced these requirements by permitting judicial review of agency compliance with the RFA and enhanced the authority of the SBA Office of Advocacy to file *amicus* briefs in court involving agency violations. In practice, this provides to the aggrieved SME court awards, attorney's fees, and costs when an agency has been found to be excessive in its enforcement of federal regulations.

A second innovation introduced by SBREFA concerns the establishment of EPA and OSHA Regulatory Review Panels to review the initial Regulatory Flexibility Analysis for each draft rule. The panel process supplements the public comment requirements established by law. Each panel consists of employees from OIRA and SBA's Office of Advocacy, the regulatory agency responsible for the draft rule and representatives of affected small entities. Since the biggest problem for SMEs seems to be tax-related burdens, as is true in most countries, it is unfortunate that a Review Panel was not established for tax compliance issues.

Although the emphasis on SME impacts is understandable, an issue that should be closely watched is the tension between treating SMEs fairly and treating them preferentially. Too much tailoring of rules could result in a "positive" discrimination mechanism that distorts competition. Undue attention to the particular interests of a very diverse set of SMEs may create a more complex regulatory system. Exception and loopholes may reduce the transparency of the system. SME concerns may also hinder important global reforms, affecting consumers as well as other firms. For instance, the SBA Office of Advocacy persuaded the Federal Communication Commission to adopt a plan that telephone carriers receive full funding to support universal service to high-cost and rural areas. This cross-subsidy from consumers to some producers to a particular class of SMEs may be imposing costs on new or high tech SMEs, among other consumers. The SBA review could, in these cases, produce contradictory results to the more complete benefit-cost analysis required by executive order.

2.3. *Co-ordination within and between levels of government*

The 1997 OECD Report advises governments to "encourage reform at all levels of government." This difficult task is increasingly important as problems and regulatory responsibilities are shared among many levels of government, including supranational, international, national, and subnational levels. High quality regulation at one level can be undermined or reversed by poor regulatory policies and practices at other levels, while, conversely, co-ordination can vastly expand the benefits of reform. Given the structure of the United States as a federation of fifty states, co-ordination of regulatory management and its reform between levels of government is of major importance.

The States have constitutional authority to issue laws and regulations in areas not pre-empted by Federal law, while the federal government also delegates authority to the states to implement many federal regulatory programmes, often on a cost sharing basis. Municipalities and local governments, such as counties, are creations of the states, and typically have regulatory and legal authorities of their own. A substantial volume of regulation is issued by the states, and, like the federal government, state governments are regulating more. "This increased rulemaking activity threatens to rival, or even replace, state legislatures as the principal source of new laws emanating from state government," an observer wrote in 1990.⁴⁷ Federal regulatory reform does not necessarily affect state regulations, and OMB has not done very much to promote reform at the state level. Many of the states, however, have employed some form of review to oversee their own regulatory agencies, and 27 states require economic impact analysis for their proposed rules.⁴⁸ This suggests that co-ordination and exchange of good practices could have significant benefits.

Expansion of federal regulation over many decades has centralised more and more regulatory authority in the federal government. The federal government has also increasingly regulated the activities of the states themselves, by mandating large new burdens and costs that have often proved difficult for state and local governments to finance. In the 1960s and 1970s "federal mandates and regulations began to rival grants and subsidies in importance as federal tools for influencing the behaviour of state and local governments".⁴⁹

A more “structural” critique also developed. In 1986, the Working Group on Federalism established by the White House concluded that “expansive, intrusive and virtually omnipotent national government” had transformed state governments from being “the hub of political activity...into administrative units of the national government”. Federalism was soon after officially established as a regulatory principle, with President Reagan ordering in 1987 that regulations should pre-empt state authority only if required by Congress or if necessary to address a problem of national scope.

The continued importance of this issue was demonstrated by the adoption in 1995 of the Unfunded Mandates Reform Act. This Act is important in a number of areas and is discussed below. However, from the point of view of federalist relations the key requirement is for a cost analysis of any bill that would impose costs on state, local or tribal governments. If a mandate exceeds \$50 million, or if the cost analysis is not attached, a procedural point of order can be raised in either chamber of the Congress (by end 1998, no bill had been blocked through this procedure, although points of order had been raised several times in the House). The Congressional Budget Office, which scrutinises compliance, has testified that this analytical requirement seemed to have a preventive effect in reducing regulatory costs.

The Federal government has recently begun to pay more attention to co-ordination of Federal regulatory actions with those at state and other levels. The Clinton executive order states that “respect” for other levels of government is fundamental, and instructs regulators to consult earlier with state, local, and tribal authorities. In some cases, progress has been seen in developing new consultation capacities to harmonise regulations among many jurisdictions. The Great Lakes Water Quality Initiative is a comprehensive plan to restore and maintain water quality in the Great Lakes Basin. It was the result of a collaborative effort by EPA, eight state governments, environmentalists, and local representatives. The flexibility for states to adapt standards to their own needs is expected to reduce the costs of protection. Such examples are not, however, very common, and there is enormous scope for further progress in co-ordinating regulatory approaches among levels of government.

3. ADMINISTRATIVE CAPACITIES FOR MAKING NEW REGULATION OF HIGH QUALITY

3.1. Administrative transparency and predictability

Transparency of the regulatory system is essential to establishing a stable and accessible regulatory environment that promotes competition, trade, and investment, and helps ensure against undue influence by special interests. Just as important is the role of transparency in reinforcing the legitimacy and fairness of regulatory processes. Transparency is a multi-faceted concept that is not easy to change in practice. It involves a wide range of practices, including standardised processes for making and changing regulations; consultation with interested parties; plain language in drafting; publication, codification, and other ways of making rules easy to find and understand; and implementation and appeals processes that are predictable and consistent. The US regulatory system is one of the most transparent among OECD Members, but some problems merit attention.

Transparency of procedures: administrative procedure laws

With some exceptions, the 1946 Administrative Procedure Act (APA) established a legal right for citizens to participate in rulemaking activities of the federal government on the principle of open access to all. The APA sets out specific requirements for administrative procedures to be followed in promulgating subordinate regulation, and hence meets the OECD benchmark in this area. The key mechanism through which participation occurs is known as “notice and comment” (described in more detail in the section on consultation, below).

Transparency for affected groups: forward planning of regulatory actions

The United States has had for many years an extensive planning system for regulations under development that ranks among the most developed in OECD countries. There are two major planning documents:

- The *Unified Agenda of Federal Regulatory and Deregulatory Actions* is published twice a year. It provides information in a common format to help the public identify which new regulations will affect them. All entries include information about the regulation’s priority, its affect on SMEs and other levels of government, whether it is part of the NPR programme, an abstract and timetable for action.
- The *Regulatory Plan* is published annually as a defining statement of the Administration’s regulatory and deregulatory policies and priorities. Entries are restricted to only the most important regulations, and contain a statement of need, a description of the alternatives considered, and description of the magnitude of risks and risk reduction expected.

The April 1999 document that combined both the *Agenda* and the *Plan* is 1 602 pages long, and contains over 4 500 entries from 63 federal departments and regulatory agencies. A subject index is included. The documents are produced through a computer regulatory tracking system maintained by the Regulatory Information Service Center, which also provides information about federal regulatory activities to the president, his Executive Office, the Congress, regulatory agencies, and the public.

The forward planning process has been a core element of the regulatory quality control system. In 1985, President Reagan ordered that federal agencies conduct, under the oversight of OIRA, an annual process of regulatory planning that would produce the *Regulatory Program of the United States Government*, to be issued under the president's signature. The planning process was intended to improve interagency co-ordination, establish the president's regulatory priorities, increase the accountability of agency heads for the regulatory actions of their agencies, and improve public and Congressional understanding of the president's regulatory objectives.⁵⁰ Regulatory planning was needed because regulation was "one of the most important and costly activities of government," yet, despite the regulatory review process set up in 1981, it was "managed far less systematically than direct government spending."⁵¹

According to OMB, regulatory planning also put into place a more rigorous and careful priority-setting process:

*Scarce government resources must be allocated according to some set of priorities. Given his Constitutional responsibilities, the President decided that regulatory priorities should not be determined unilaterally by each agency. Rather, these priorities should be selected by the President's Administration as a whole, through a process that takes into account a wide spectrum of agency demands and Presidential policies.*⁵²

The 1993 Clinton executive order retained forward planning, and put more emphasis on its value for communication and consultation. The regulatory plan made it possible for the citizen "to be a well-informed participant in the regulatory matters that affect your life," Vice-President Gore wrote to the readers of the 1997 Regulatory Plan.⁵³

Transparency for affected groups: use of public consultation

Public consultation is highly developed in the United States. Almost all federal regulations are developed through mandatory administrative procedures intended to ensure public consultation and openness. These "notice and comment" procedures dominate the rulemaking process in Washington by establishing the channels through which multiple interest groups strive to influence the regulatory decision by developing empirical or legal arguments supporting their positions.

The Administrative Procedure Act, enacted in 1946, establishes minimum procedural requirements for rulemaking. While it leaves agencies great flexibility to develop procedures, the Act requires that an agency publish a proposed rule in the Federal Register. Except for some widely used exceptions,⁵⁴ the public must be given at least 30 days to comment in writing and the agency must consider any comments received. The comments themselves are made public via the establishment of a legal rulemaking "record", which contains all factual material received and potentially relied upon in the regulatory decision. When an agency publishes a final rule, it must explain the factual and logical basis for its decision, how it reached its conclusion, and how it dealt with the public comments received. Where important new material is received, there may be a need for more than one round of comments. Rules must be published not less than 30 days before becoming effective.

Written comments may be supplemented by a public hearing. Hearings tend to be formal in character, with limited opportunity for dialogue or debate among participants. Experimentation with "on-line" hearings has also commenced. A separate consultation process on paperwork requirements is established by the Paperwork Reduction Act, which is described below.

The American system of notice and comment has resulted in an extremely open and accessible regulatory process at the federal level that is consistent with international good practices for transparency. The theory of this process is that it is open to all citizens, rather than being based on representative groups. This distinguishes the method from those used in more corporatist models of consultation, and also from informal methods that leave regulators considerable discretion in who to consult. Its effect is to increase the quality and legitimacy of policy by ensuring that special interests do not have undue influence.

That said, there are serious problems with consultation that are rooted in the legalistic and adversarial tendencies of the American regulatory system. Notice and comment has tended to develop into a legalistic, formalistic process that can prevent rather than promote dialogue, co-operation, and communication. The role of the formal record in subsequent court challenges has too often meant that interest groups use it as the first stage of litigation, rather than as an honest inquiry. This has helped to discredit consultation. The Clinton Administration noted that, in the past, the agencies had already made up their minds even during the comment period and were unlikely to make changes based on public comment.⁵⁵

Too, effective ability to participate is often limited by the complexity of the rules in question, particularly where scientific or technical matters dominate. The failure of regulators to clearly state the implications of regulatory decisions leaves the field to well-funded experts representing highly organised interests. Rather than organising information and communication, regulators have a passive role, in most cases simply waiting for the public to respond.

The key task is to marry a high level of transparency with development of a less adversarial system for consultation. The National Performance Review considered the performance of existing consultation processes. It concluded that, notwithstanding the extensive consultation processes already in place, “without exception”, all groups wanted earlier and more frequent consultation opportunities. Moreover, while these were potentially costly, there were significant potential benefits in terms of greater regulatory quality and compliance. NPR recommended that agencies investigate more flexible and more interactive means of consultation, provide assistance to regulated groups to enable them to participate more effectively, increase programme evaluation, and make better use of information technologies.

The 1993 Clinton executive order, too, dealt with a number of these concerns. Consultation periods for proposed regulations have increased from an average of 30 to an average of 60 days. Agencies were ordered to involve affected parties earlier in the regulatory development process and to use consensual mechanisms such as negotiated rulemaking. There has been progress, as noted above in the section on state co-ordination and below in the discussion on negotiated rulemaking (though assessments indicate that this approach has been unsuccessful to date). Another important reform with the potential to transform access to the US consultation system is that public comments are now solicited through the Internet, which has noticeably increased participation. The United States probably conducts more communication with the public on regulatory matters through the Internet than any other country. The limitations of this method in providing equal access in practice have not, however, been adequately assessed.

Transparency in implementation of regulation: communication, compliance and enforcement

Once a regulation is adopted, it is easily accessible to affected entities. To become effective, final regulations must be published in the *Federal Register*, which is also available on-line. Final regulations are indexed and published in the consolidated *Code of Federal Regulations*, which is also available on-line. The *Code* provides a comprehensive view of the regulation in force at a given time.

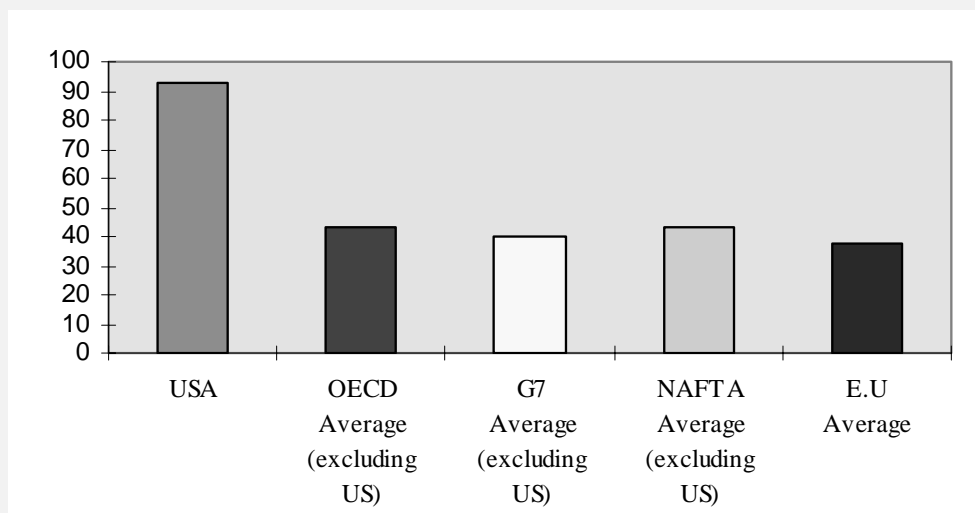
A “simplicity and clarity” policy was adopted in June 1998 when President Clinton instructed civil servants to write all documents “in plain language.” This is the latest effort in a long series of battles dating from the Carter Administration that seem to have had little success. One notable effort to improve communication of regulatory text has been the publication by some regulators of plain language “Small Business Compliance Guides” distributed by “outreach” programmes.

Improving enforcement strategies became a national priority only recently, though concerns about a possible decline in the capacities of the regulatory agencies to adequately enforce regulations have been prominent for many years. Budget cuts were, it was feared, disproportionately focused on enforcement capacities, indiscriminately reducing the performance of good and bad regulations alike. Comparative analysis sheds no light on whether the United States suffers lower levels of compliance than do other countries, or whether the compliance trends are moving in the right direction. Almost nothing is known on this topic in any OECD country.⁵⁶

The Vice-President, through the National Performance Review, instructed agencies to shift the focus of enforcement activities away from “paperwork violations” to an emphasis on performance results and to move away from adversarial relations with regulated parties toward a more co-operative approach. Several specific innovations are discussed below in Section 3.2. Compliance assistance and enforcement issues for SMEs were also targeted in the 1996 SBREFA. The Act obliges agencies to publish compliance guides for all rules with a significant small business impact. SBREFA also establishes a complaint process whereby any SME can complain about enforcement actions to the new SBA Ombudsman or one of the 20 small business regulatory fairness boards established across the country.

Box 5. Transparency of regulatory systems in selected OECD countries

Based on self-assessment, this broad synthetic indicator is a relative measure of the openness of the regulation-making and regulatory review system. It ranks more highly national regulatory systems that provide for unrestricted public access to consultation processes, access to regulation through electronic and other publication requirements, access to RIAs, and participation in reviews of existing regulation. It also ranks more highly those programmes with easy access to licence information, which tends to favour unitary over federal states. The United States scores very highly on these criteria relative to other OECD countries. It loses points due to the absence of single contact points for obtaining information on business licence and permit requirements.



Source: OECD Public Management Service.

3.2. Choice of policy instruments: regulation and alternatives

A core administrative capacity for good regulation is the ability to choose the most efficient and effective policy tool, whether regulatory or non-regulatory. In the OECD area, the range of policy tools and their uses is expanding as experimentation occurs, learning is diffused, and understanding of markets increases. At the same time, administrators face risks in using relatively untried tools. Bureaucracies are highly conservative, and there are typically strong disincentives for public servants to be innovative. This is particularly the case in a litigious environment such as the United States. A clear leading role — supportive of innovation and policy learning — must be taken by reform authorities if alternatives to traditional regulation are to make serious headway into the policy system.

Here, the US system presents both strengths and weaknesses. Legal liability for actions that harm others is itself a strong alternative to government regulation in many social areas. Because liability is outcome oriented and based on economic incentives, it is likely to be in many cases more cost-effective than regulation at reducing risks, but the cost-effectiveness of some aspects of the US tort system has been questioned. High legal expenses and the risk of potentially large punitive damage awards in liability are claimed to increase business costs unnecessarily and reduce innovation and risk-taking. The number of civil cases has risen to 2.7 per cent of GDP, four to five times the levels found in other OECD countries.⁵⁷

There is a long history of efforts to expand the use of innovative instruments. In 1978, President Carter issued an order to regulators — to install what he called "common-sense management for the regulatory process" — to show that "alternative approaches have been considered and the least burdensome of the acceptable alternatives have been chosen."⁵⁸ Similarly, in 1981, the Reagan executive order required regulators to ensure that "Among alternative approaches to any given regulatory objective, the alternative that maximises net benefits to society should be chosen." Crucially, assessment of alternatives was to be documented through regulatory impact analysis. "If regulatory reform is judged useful according to whether it improves the cost-effectiveness of regulation, then regulatory impact analyses that contain estimates of the costs and benefits to society of alternative regulatory approaches is a necessary condition for regulatory improvement," OMB wrote.

The current Clinton executive order as well as the National Performance Review also make clear that alternatives such as market incentives are preferable to command and control regulations. A considerable amount of effort has gone into encouraging regulators to be more innovative by using three main approaches: performance standards, market incentives, and information strategies.

Anecdotes suggest that innovative approaches are beginning to pose genuine competition to old styles of regulation. Expectations are higher that alternatives will be seriously considered, and several approaches now underway are useful experiments that should, if successful, help persuade a public administration that is extremely risk-adverse of the benefits of innovation.

Yet progress continues to be very slow. Despite two decades of effort, the US regulatory system still relies mainly on command and control rules. Progress is most evident in the environmental area, but overall there is little sign that the diversity and scope of alternative instruments has increased very much in recent years, and in fact the US system seems less innovative than some other OECD countries, such as the Netherlands. The 1993 NPR found that regulators continued to over-rely on command and control regulations, and blamed several factors, including:

- Congressional and agency lack of know-how about innovative approaches and how to design them.
- Congressional distrust of agencies, which means that Congress does not give agencies the flexibility to try new approaches.
- Agency and congressional distrust of the regulated public.

In addition, the legalistic culture and procedural complexities that inhibit innovation in the US public sector are probably major reasons for the cautious approach to regulatory innovations. The NPR recommended creation of a regulatory working group to consider new, creative and more effective alternatives and approaches to regulating (the interdepartmental Regulatory Working Group has made some effort to carry this out), and development of guidance on alternative instruments for regulators (not yet implemented).

A source of innovative and experimentation in the US regulatory system is the 50 states, although the states have not been as innovative in the regulatory area as in other areas of public policy. One reason may be that the federal government, by creating a rigid national regulatory regime, stifles innovation at lower levels. A key problem, according to the Environmental Council of the States (ECOS), was that federal agencies have no procedures for dealing with new ideas. That is, innovations do not fit into standard operating procedures, and hence cannot be pursued effectively by civil servants. A solution was to create new procedures through which civil servants could legitimately deal with experimentation and innovation. The 1998 ECOS-EPA Agreement to Pursue Regulatory Innovation "creates a path and a process that is clear to everyone" for how EPA will deal with state innovations.⁵⁹ The agreement contains operating principles giving states greater scope to implement innovative ideas to achieve better environmental outcomes and giving states and regional EPA offices the freedom to test different projects, as well as providing monitoring and information-sharing of the results.

Market incentives. Properly structured, economic incentives offer two great advantages over traditional "command and control" regulation. First, they allow business and others to achieve regulatory goals in the least costly manner. Second, market incentives reward the use of innovation and technical change to achieve these goals. There is some experience with the use of market-based instruments in the United States. The most innovative policy field is environmental protection, where a wide range of instruments is employed. The most celebrated is lead phasedown in gasoline (1982-1987), which persuasively demonstrated the potential effectiveness of credit trading: lead emissions in 1997 were 2 per cent of 1970 emissions. While the United States has played a pioneering role in the use of tradable permits (and is among the small number of countries where these are used to any significant extent), it is striking to see that the tax instrument is hardly used, especially in energy and transport-related issues. This is exactly the reverse of the situation in most OECD countries.

In the last decade, marketable permits are slowly increasing their reach, due in part to the increased complexity of pollution controls. The EPA views tradable permits as offering both the possibility of stricter standards and better environmental protection, due to the lower unit costs of pollutant reduction, as well as holding "promise for addressing problems, such as polluted runoff, that have not been brought under control through traditional regulatory means." Standardised regulatory approaches to control of emissions from factories, for example, do not work well with non-point sources of pollution that require flexible and source-specific solutions.

In particular, the EPA states that emissions trading "has become a standard environmental management tool, with the number of national programs offering this compliance option increasing markedly in recent years".⁶⁰ Recently, the Clinton administration has promoted the use of an international permit trading system as the most cost-effective to reduce greenhouse gases. There are several examples of emissions permits trading at local and regional levels. For example, CFC production allowance trading (1990) was quite successful. Southern California's Regional Clean Air Incentives Market (RECLAIM) aims to reduce industrial emissions by 80 per cent by 2010. A general set of rules for local air-pollution-permit trading has been proposed by EPA. This set of rules, called the Open Market Trading Programme, allows any state whose air quality problems and planning for compliance with federal air-pollution-laws are consistent with emissions trading to adopt a trading programme without a lengthy EPA review process.

Examples of trading arrangements in other policy areas include:

- Marketable permit programmes for water rights in the western United States have been active for many decades. In contrast to the active water market in Colorado, years of efforts to create a state-wide market for water in California — to move water from agricultural to urban uses — have been unsuccessful, partly because of complex property rights rules and numerous oversight bodies.⁶¹
- Major US airlines are trading landing slots at busy airports at prices in the range of US \$1 million per slot.
- The New Jersey programme of tradable Regional Contribution Agreements allows a town to meet its legal obligation to provide low- and moderate-income housing by transferring the housing requirement to another willing municipality through a regional contribution agreement (RCA). An RCA is a cash payment from one municipality (usually suburban) to another municipality for the purpose of building or refurbishing low- and moderate-income housing in the receiving municipality. These obligations have been recently traded at a cost of \$27 000 per unit.⁶²

Other economic incentives used in the environmental area include tax incentives, including a federal incentive that encourages commuting, and pricing reforms that ensure that environmental costs are better reflected in consumer choices for services such as household garbage collection and disposal. Proposed policies for the year 2000 on climate change technologies would establish tax credits for energy-efficient purchases and renewable energy.

Information approaches. One of the most powerful alternative approaches to regulation is the use of information to empower citizens and consumers to take actions in their own interests. Typically for the United States, information has been approached in many policy areas from the perspective of a legal “right to know” rather than a flexible programme response to problems. There are many interesting examples of the use of information in the United States as a substitute or complement to other forms of regulation.

- Drinking water information for consumers. Stating that “an informed and involved public is necessary to keep [a high] level of safety” in water quality,⁶³ the EPA proposed in February 1998 to provide consumers with better information about the quality of water in the community. Water suppliers would, for the first time, be required to report to their customers at least once a year on the quality and sources of local drinking water, its compliance with health standards, likely sources of any contaminants, and the risks of any contaminants. This “consumer confidence reporting” would apply to all of the nation’s 56 000 community water systems.
- Toxic release inventory. The 1986 Emergency Planning and Community Right to Know Act mandated that plants communicate information about toxic releases to local communities. Some 66 000 firms are covered nation-wide. Together with recent changes in 1997, the information is intended to provide a picture of how toxic chemicals are being managed within communities, and thereby improve the accountability of the private sector to those who may be affected by its activities.
- Consumer labelling. In 1996, EPA launched an initiative to improve consumer labelling information on pesticides, cleaning supplies, and other household products. Labels are being made more user friendly, with phone numbers for more information, and efforts are being made to standardise environmental information and storage and disposal instructions. A consumer education programme is planned to improve consumption of the information provided.

Box 6. Marketing pollution permits - clean air at lower cost

Marketable permit or obligation programmes provide administrators with an alternative to traditional regulatory techniques. If developed and applied appropriately, they can reduce the cost of regulation, increase compliance flexibility, support economic-growth goals, and reduce the adversarial nature of regulation while still achieving regulatory goals.

Perhaps the best known example of such trading is the acid rain programme operated by EPA that is designed to reduce US sulfur dioxide emissions by 10 million tons annually from 1980 levels. In the programme, emitters of SO₂, a precursor to acid rain, have been issued a finite number of allowances (permits) that can be used over the next 50 years. SO₂ allowances are denominated in tons of SO₂, but not by year. This is because acid rain is a cumulative problem, so the absolute amount deposited matters more than the timing of the deposition.

There are two deadlines for individual plants to reduce emissions: at the end of 1995, SO₂ emitters had to achieve a first level of emissions reductions. A second round of reductions must be achieved by 2000. The number of allowances issued to individual plants reflects these reduction targets. Plants that over-comply and have excess allowances may sell them.

SO₂ trading regulations were developed from 1991 to 1992, and the programme was launched in 1992. Strict enforcement measures are built into the federal legislation, including automatic fines (indexed to inflation), plus a requirement to purchase the missing allowances in the next period, for failure to demonstrate ownership of sufficient allowances. For intentional (criminal) non-compliance, heavy fines and jail terms are possible consequences. As of March 1996, there have been no violations (Kruger, 1996). CEMS technology enables EPA to match output with allowances. When allowances are traded, the buying and selling entities must register the trade with EPA. The traders' computerised inventories are updated so that compliance in terms of the new levels of allowances can be monitored.

An important design feature of the SO₂ programme that was debated in Congress concerned how much electric utilities should have to spend to reduce SO₂ emissions. To estimate cost, an estimate of the value and volume of tradable allowances was needed. Utilities predicted that a one-ton allowance would cost roughly US\$1 000; USEPA thought between US\$500 and US\$600. In fact, allowance prices originally (in 1992) traded for \$250, and as of June 1995 were trading for \$140, well below any prediction (Wald, 1995).

The original over-estimation of allowance prices had important public policy implications. Part of Congress's decision on how much acid rain reduction to require was based on predictions of how much the clean-up would cost. That is, Congress not only considered the health, ecological, and other impacts of acid rain when choosing a target for reductions, but it also had in mind a reasonable spending target for electric utilities. Because the cost of allowances was over-estimated, the overall SO₂ reduction goal is lower than it might have been. While some criticism has been levelled at the programme for this reason, it overall has been viewed as a success, since compliance costs have fallen dramatically.

There is a great deal of speculation as to why the cost of SO₂ allowances fell so far below predicted levels. Among the possible explanations are that utilities purposely overestimated allowance cost, aware of the link between allowance cost and total obligation to reduce SO₂ emissions (Wald, 1995), that the cost of natural gas, a low-sulphur substitute for coal, has fallen more than expected, that costs of low-sulphur-coal mining and transport by rail are lower than predicted, making low-sulphur coal a more attractive substitute for high-sulphur coal, and that the price of technologies that reduce sulphur emissions, such as scrubbers, has fallen (Palmisano, 1995). The unexpected but key link between SO₂ reductions and railroad deregulation is another example of the synergies between regulatory reforms in a broad-based reform programme.

The programme has produced significant, additional, unexpected cost savings, and reductions in emissions are ahead of schedule. Estimates of cost-savings just from allowing trading range from 25 to 43 percent, and other factors, such as the cheaper transport of coal, further reduced costs. For example, the EPA forecast in 1990 that the cost of SO₂ reductions in 2010 would be between \$2.6 billion and \$6.1 billion (in 1995 dollars). But a 1998 study projected that these costs would be just over \$1 billion (in 1995 dollars).⁶⁴

Voluntary, market-driven, and other co-operative approaches. Voluntary, market-driven, and co-operative approaches are interesting because they offer the advantages of speed, consensus, and flexibility,

as opposed to arduous, adversarial, and formal rulemaking. Costs of compliance can be lowered, while incentives to comply can be strengthened compared to traditional sanctioning approaches. There is a broad spectrum of experimentation underway in OECD countries to expand use of these policy instruments. The use of market-driven standards has a long history in the United States, but the United States lags behind in the use of other voluntary and co-operative approaches. This is largely because relations between the public and private sector are legalistic and rule-driven rather than results-oriented, and co-operation between firms is highly constrained due to strict competition policy regimes.

Market-driven standards are used frequently in the United States relative to other OECD countries (see background report in this volume on Enhancing Market Openness through Regulatory Reform for a detailed discussion). The US standards development process is mostly industry-led, operating on a private, voluntary basis through more than 600 private standards-setting bodies. Government policy with respect to standardisation directs Federal agencies to participate in voluntary standards development activities and to use voluntary consensus standards in lieu of purely government standards except where inconsistent with law or otherwise impractical. This recognises that many voluntary consensus standards are appropriate or adaptable for the Government's procurement and regulatory purposes. Recently, the US preference for market-driven regulations has been seen in the government's approach to Internet and electronic commerce: "In our view, the voluntary, open, market-driven and consensus-paced standards development process has proven effective in balancing diverse and often competing interests in the computer and telecommunications market."⁶⁵

Environmental programmes experimented with a variety of voluntary programmes in the 1990s, under names such as the Pesticide Environmental Stewardship Program, Encouraging Environmental Excellence, and Common Sense Initiative. A recent study⁶⁶ found that voluntary programmes in the United States combine the features of the unilateral, negotiated, and public voluntary approaches employed in the European Union. In the United States, Voluntary Agreements (VAs) are primarily employed to address legislative shortcomings. Most US voluntary efforts are co-operative, non-mandatory strategies.

Implementation problems have led to lower-than-expected environmental results for all VA categories. Among the different types of VAs employed in the United States, programs designed to reduce greenhouse gas emissions and a subset of toxic chemicals have contributed to emissions declines. However, weak evaluation methods likely caused EPA to overstate the environmental effectiveness of both climate change and prevention programs. In all cases, VA assessment is hampered by program novelty, lack of data, and weak monitoring and evaluation methods. In most cases, it is difficult to attribute environmental changes exclusively to voluntary programs. Due in part to the lack of environmental data, virtually no studies have been developed to demonstrate whether voluntary approaches are efficient.

The data that do exist identify a number of "soft effects." Participants in most VAs cite public opinion and/or regulatory goodwill as significant benefits. In some cases, VAs may confer competitive advantages to participants as well. Improved goodwill may indirectly lower costs associated with permitting and reporting, as well as minimise the threat of more stringent regulation. Soft factors may indirectly reduce administrative and abatement costs. At a minimum, VAs have the potential to promote interaction among groups who normally interact through the regulatory process as adversaries. Such VAs provide more opportunities for stakeholder participation than the status quo. However, implementation is hampered by the lack of clearly-defined administrative, monitoring, and participatory procedures. Thus, VAs — particularly unilateral and negotiated approaches — lack credibility among environmental groups and some industries. To promote trust, VAs must be made more transparent.

As with other innovative approaches, federal laws often impede VA implementation, particularly industry-led efforts and public projects that employ negotiation.⁶⁷ As a result, voluntary approaches remain largely “marginal” to federally-mandated air, water, waste, and toxics programs. Implementation may be strengthened by taking legal factors into consideration. However, in the United States, it is likely that the effectiveness of VAs will remain limited until the existing legislative framework is changed.

Co-operative approaches are more promising in the area of occupational safety and health. The design of rules and monitoring and enforcement regimes can encourage compliance by providing incentives or rewards for high voluntary compliance and compliance innovation. A recent survey of research concluded that, although empirical results are sketchy, where enforcement style were “more co-operative, it was more effective at reducing injury rates than where enforcement had been more adversarial.”⁶⁸ One example is an Occupational Safety and Health Administration (OSHA) experiment initiated in 1993 in Maine. The Maine OSHA office used its databases to identify 200 employers with the highest number of injuries. Each was given work site specific injury and illness profiles and then asked to ‘choose their OSHA’: either they could use OSHA’s help to survey hazards, and correct and implement worksite safety systems or they would be targeted for more frequent traditional comprehensive inspections because of their risk prioritisation. All but 2 firms chose partnership with OSHA.

The results were encouraging. Total workers compensation claims dropped by 35 per cent in those worksites during the program; employers identified 95 800 hazards and abated 55 200 (in comparison with the 36 780 that OSHA inspectors had discovered and cited in the previous eight years at those sites); at least 320 worksite health and safety committees were established; and nearly 60 per cent of employers reduced their injury and illness rates even as fines and inspections diminished.⁶⁹ OSHA hoped to expand the most successful features of this program nation-wide, although a recent court case has stopped expansion. Ironically, the innovative OSHA programme was overturned in federal court because it did not go through the rulemaking process, with notice and comment procedures.

The OSHA Voluntary Protection Program recognises achievement by companies that successfully integrate a comprehensive safety and health program into their total management system. Employers with exceptional programs receive special recognition including: the lowest priority for enforcement inspections, the highest priority for assistance, regulatory relief, and penalty reductions of up to 100%. For firms who are well intentioned but have room for improvement, a sliding scale of incentives is offered. The results: Overall injury incidence rates were 55 per cent below expected average for similar industries. Overall, participating companies were 51 per cent below expected lost workday injuries in similar industries, saving \$94 500 000 for 3 500 lost work-days avoided. Many sites had production improvements, reduced absenteeism and lower workers’ compensation costs.⁷⁰

Negotiated rulemaking. Negotiated rulemaking, new to the United States, is familiar in most OECD countries where consensus-based approaches to regulation are used. Involvement of affected parties in decisions seeks to improve regulatory performance in several ways: by drawing on the expertise of the regulated to improve the technical quality of regulation; by fostering “ownership” of the outcome and, hopefully, the level of consent and voluntary compliance; by increasing the legitimacy of regulations; by diminishing the risk of hostile litigation by achieving a high degree of consensus; and by reducing the time to develop and implement new rules.

Box 7. Regulatory innovation through HACCP

The US Food and Drug Administration was an early advocate of an alternative form of regulation known as “process regulation”. This approach requires producers to document and analyse the different stages of the production process, identifying key points at which hazards arise and putting into place site-specific strategies to manage them. The idea is that producers are better at identifying hazards and developing lowest-cost solutions than is a central regulatory authority. This approach is particularly useful where there are multiple and complex sources of risk, and *ex post* testing of the product is either relatively ineffective or prohibitively expensive.

The FDA’s Hazard Analysis Critical Control Points (HACCP) programme to regulate seafood safety shifts the basis of regulation to one consistent with quality assurance principles, rather than the older approach focused on verifying “end of pipe” compliance. The seven key HACCP components are:

- Hazard analysis: identification of likely hazards that could occur in specific products as a result of specific processes.
- Critical control points (CCPs): the key elements of the production process in terms of potential for health hazards to arise in the absence of adequate control measures.
- Critical limits: measuring levels of control performance at CCPs.
- Monitoring: keeping watch over CCPs to assess if controls are within critical limits.
- Corrective action: steps to be taken when monitoring indicates that critical limits are exceeded.
- Record-keeping: recording and maintaining information about results of monitoring, corrective actions and verification.
- Verification: reviewing all HACCP components periodically or when a production element changes.

FDA’s economic analysis concluded that the present value of benefits of HACCP, compared with existing regulatory approaches, would be in the range of \$1.4 billion to \$2.6 billion, with up to 58 000 illnesses due to contaminated seafood being avoided annually.

HACCP approaches have now been recommended by the UN based Codex Alimentarius Commission and a number of other countries (*e.g.* Canada in relation to seafood) have also moved toward HACCP.

Source: This discussion is adapted from Chenok, Daniel J. (1997), “Flexibility Through Public-Private Partnerships: Prevention and Harmonization in FDA’s Seafood HACCP Regulatory Alternative,” in OECD Public Management Occasional Papers No. 18, *Co-operative Approaches to Regulation*.

The legalistic environment for rulemaking in the United States has discouraged consensus-based approaches. The Negotiated Rulemaking Act of 1990 formalised a legal process to bring stakeholders into the process of developing rules at an early stage. It sets out a range of process requirements that establish a framework for attempts by regulators to reach consensus among major regulated groups on new regulations. It is carried out via an iterative, committee-based approach to rule development, with safeguards to ensure that all significant interest groups have an opportunity to request involvement. The negotiation is an additional element in the rulemaking process. The agreed text is published as a proposed rule and undergoes subsequent consultation in the normal way.

While there were some experiments with negotiated rulemaking in the 1970s and 1980s, the passage of the Negotiated Rulemaking Act in 1990 gave it a higher profile in the regulatory system. This innovation received significant political support. A 1993 executive order asked agency heads to identify potential areas for negotiated rulemaking. By the end of 1996 — or almost six years after the introduction of the Act — 17 agencies had initiated at least one negotiated rulemaking. The total number of negotiated rule-makings was 67, although approximately one quarter of these predated the introduction of the 1990 Act which formalised the process. Agencies had abandoned the process without any consensus in at least 13 of these cases.

As these figures suggest, negotiated rulemaking carries risks. The process can be resource intensive and yield little if agreement is not reached. The parties may use the process as a rent seeking opportunity by trying to insert particular advantages for their constituents into the regulation. The low rate of use suggests that regulators are unconvinced as to the benefits of using the process or, alternatively, that the situations where negotiated rulemaking can be useful are rare.

Early assessments⁷¹ suggested that significant time savings had been achieved by negotiated rulemaking, but a subsequent comprehensive study⁷² disputes this finding and adds that not only has the process failed to save time, it has also required a more intensive use of agency resources. This observation has intuitive merit since the negotiated rulemaking process is conceived formally as an addition to processes already mandated in the Administrative Procedure Act. The notice and comment procedures still apply at the conclusion of negotiations. This design of negotiated rulemaking reflects a desire to maintain an “open” process of consultation in all cases and avoid charges of “corporatism” and lack of transparency, but results in a process still mired in formalistic and time-consuming steps.

Similarly, evidence suggests that negotiated rulemaking has failed to reduce the incidence of legal challenge to regulations. Analysis of EPA’s experience (EPA is the largest user of negotiated rulemaking) indicates that the incidence of litigation is no lower than for conventionally made rules, despite the fact that the criteria for use imposed by the Act would tend to favour the selection of rules which were likely to be less prone to litigation. Possible explanations for this observation include the exclusion of affected interests from the negotiations, the extent to which the final rule reflects the agreed consensus and conflict over matters not dealt with in the agreements. It has also been suggested that, by raising expectations of accommodation of private interests in the rulemaking process, regulatory negotiation may make parties more sensitive to outcomes adverse to their interests and so more inclined to litigate.

Despite these concerns, it remains possible that negotiated rulemaking has improved the technical quality of regulations. It seems to work best when there is a defined number of players, and the issue is concrete and well-defined. As noted above, attempts to reform consultation procedures in general have pointed toward the need for more intensive, iterative procedures which commence far earlier in the development of regulatory proposals. Negotiated rulemaking appears to respond to all of these requirements. Moreover, the theoretical potential for it to compromise regulatory quality via the insertion of self-serving elements in proposed rules by the parties must be much attenuated by the very open “notice and comment” process which must be undertaken after the negotiations and by the real threat of subsequent litigations.

There is also the possibility that a number of the shortcomings of negotiated rulemaking result at least partly from relative inexperience with its use by all parties. If so, this may be a self-sustaining problem, as agencies may be reluctant to extend their use of the process precisely because early experiences are not favourable.

3.3. *Understanding regulatory effects: the use of Regulatory Impact Analysis (RIA)*

The 1995 *Recommendation of the Council of the OECD on Improving the Quality of Government Regulation* emphasised the role of RIA in systematically ensuring that the most efficient and effective policy options were chosen. The 1997 *OECD Report on Regulatory Reform* recommended that governments “integrate regulatory impact analysis into the development, review, and reform of regulations.” A list of RIA best practices is discussed in detail in the OECD’s 1997 report, *Regulatory Impact Analysis: Best Practices in OECD Countries*.⁷³ This report provides a framework for the following description and assessment of RIA practice in the United States.

Regulatory impact analysis was pioneered in the United States, beginning in 1974 with inclusion of benefit-cost analysis in Inflation Impact Assessments. In fact, a review of OECD countries found that the United States was the first country to adopt broad requirements for benefit-cost analysis for regulation.⁷⁴ Full RIA has been required by executive order for all major social regulations from 1981, with the OMB responsible for quality control. The value of RIA has been considerably enhanced by its full integration into public consultation process. Today, quantitative benefit-cost analyses are prepared for over 90 per cent of major social regulations, but only 18 per cent of major economic regulations.⁷⁵ RIA is not typically prepared for primary legislation.

Under the current executive order, the design of the federal RIA programme is based on several key threshold, cost-effectiveness, and benefit-cost principles (noted in Section 2):

- The government should not regulate unless there is adequate information concerning the need for and consequences of regulatory action.
- Regulatory action should not be undertaken unless potential benefits to society justify potential costs.
- Regulatory objectives should be chosen to maximise the net benefits to society.
- Among alternative approaches to a given objective, the one chosen should be that which maximises the net benefits.

The trend today is to further standardise and upgrade RIA methods by establishing binding legal requirements, rather than relying on executive orders. A 1995 law (UMRA) requires cost-effectiveness analysis of a “reasonable number” of alternatives for any regulation that would require expenditures of more than \$100 million by state and local governments, and \$100 million by the private sector in any one year. This is an important step, though the UMRA cost-effectiveness test is weaker than the benefit-cost test contained in the executive order, and the “expenditures” threshold is less analytically sound than the broader “effects” test, including both costs and benefits, in the executive order. Proposals to strengthen the legal framework for regulatory analysis by legislating the benefit-cost principle, by establishing independent peer review outside of OMB, and by subjecting RIA to judicial review were unsuccessfully pursued in the Congress through 1998.

At the same time, independent review by OMB has become more selective. While an average of over 2 000 agency rules and 75 RIAs per year were reviewed by OMB during the 1980s and early 1990s, this fell to fewer than 500 rules by 1996, although the number of RIAs remained roughly the same. This is the result of a policy of focusing resources on more important rules to maximise the expected benefits of the review process. In addition, OMB has attempted to become more closely involved with agencies during the drafting of major rules. Input at an earlier stage of development potentially maximises OMB’s ability to achieve change, and indeed some 60 per cent of regulations are changed during OMB review. It is also argued that this targeted approach allows routine regulations to be completed more quickly, speeding up the clogged regulatory process.⁷⁶

This change in policy has coincided with a sharp reduction in the percentage of rules that OMB returned to the agencies to be revised — from an average of 1.2 per cent of those reviewed in the period to 1993 to 0.2 per cent from 1994-1996. The implications of this with respect to OMB oversight of regulatory quality are unclear. Absent other factors, the drop seems counter-intuitive, given the focus on more important regulation, as potential gains from improvements are greater for these regulations. Moreover, if reviews have become more thorough and intensive, discovery of cost-effective improvements

seems more likely. On the other hand, as OMB argues, earlier involvement with regulators during the development phase may have reduced the likelihood that regulations containing major problems are sent to OMB for formal review, and problems are more easily worked out during OMB review.

Evidence on the results of RIA. Evidence on the value-added of RIA indicates that it has significantly improved the quality of some regulations, but that implementation is uneven across policy areas. In part due quality problems and in part to legal mandates that prohibit its use in some areas, RIA has not been successful at preventing the adoption of many low-quality regulations.

The evidence is building that RIA, when well prepared, helps increase the net social benefit of regulations. As long ago as 1981, an analysis of regulatory proposals critiqued by a Carter-era regulatory analysis review group showed that about one third were significantly improved. In 1987, the EPA analysed its experience with the use of RIA in 15 cases and concluded that its \$10 million expenditure on RIA had reduced the costs of proposed rules by \$10 billion, or a benefit/cost ratio of 1000 to 1. The GAO found in 1998 that that, out of 20 RIAs, 12 were used to identify the most cost-effective approaches, and that seven of the other RIAs were used to define the scope and timing of implementation.⁷⁷ The suggestion that RIA is apparently genuinely integrated into policy processes is very positive, since many OECD countries are encountering difficulties on this point. Responding to concerns that RIA systematically overstate likely costs, a recent study of the limited number of cases where both pre- and post-implementation cost estimates exist found that, prior to 1981, compliance costs for new regulations were usually over-estimated, but that since 1981 the accuracy of estimates has improved and “the balance has been more equal.”⁷⁸

There is also evidence of a profound cultural change among regulatory agencies, insofar as the need to take economic impacts into account is much more widely accepted than in the 1970s. Viscusi presents data on the cost effectiveness of regulations from several agencies and argues that there is a clear correlation between internal agency attitudes and the efficiency of the regulations.⁷⁹ For example, a Department of Transportation policy to issue only regulations that are estimated to save statistical lives at a cost of less than \$3 million is consistently applied in practice.

Yet there are substantial weaknesses in the quality and completeness of the analysis. In its 1997 report to Congress, OMB was unable to present aggregate cost and benefit numbers for 41 major regulations reviewed, due to lack of data. Of the 41 regulations, 21 required substantial additional private expenditures, but only in eight cases did agencies provide monetised benefits estimates, while cost estimates were presented in 16 cases. Hahn⁸⁰ finds that, of 92 health, safety and environment rules, in fewer than 20 per cent of the RIAs were benefits quantified in monetary units and shown to justify costs. His analysis found considerable inconsistency — within and between agencies — in assumptions and methodology. These included the use of different discount rates, the failure to present BCA in net present value terms and wide variations in assumed benefits for reduced death and injury rates. These findings of inconsistencies and incompleteness in RIAs were again corroborated by GAO’s 1998 review of RIAs. Another dimension of quality is accuracy. The infrequency of efforts to “look back” and assess the real impacts of regulations against the *ex ante* projections in the RIAs means that there is very little information about how accurate RIAs have been in presenting the consequences of decisions.

While full quantification of the benefits of regulation is perhaps unachievable, Hahn suggests that significant benefits would be expected (both directly and indirectly) by “making key assumptions explicit, using best estimates and appropriate ranges to reflect uncertainty, providing estimates of the NPV of benefits and costs and summarising sensitivity analyses and base case results” In addition, “Agencies should also do more peer review to improve quality of analysis, but the nature of this peer review needs to be carefully designed”.⁸¹ Use of independent peer review panels have been advocated by some Members of Congress and by OMB.

Box 8. Regulatory budgeting: a new way to control regulatory costs?

An innovative policy tool that has been examined in the United States is regulatory budgeting, which uses traditional budgeting concepts to better manage aggregate regulatory costs. The regulatory budget concept is modelled on the fiscal budget approach, in which an agency or programme head is given a budget ceiling, within which funds are allocated among competing needs. In the regulatory budget, however, the ceiling would be measured by the economic costs of regulatory compliance borne by the private sector. That is, the regulatory body would be given a ceiling on new regulatory compliance costs.

While this tool has had limited practical implementation to date, it has the potential to transform the transparency, accountability, and incentives of regulatory decisions. Recent estimates of the annual cost of federal regulation are in the range of \$280 - \$700 billion, and projections show the costs of regulation continuing to climb. These costs can be seen as a form of indirect taxation because the economic effects of taxes and regulatory costs are similar. From this perspective, regulation is a mechanism for government spending and regulatory costs are a form of government expenditure. Regulatory expenditures are the major government expenditure still “off-budget”, that is, not included in the accounting and control system called the fiscal budget.

Budgeting would produce four major benefits when applied to regulatory costs. First, a budgeting approach would require explicit consideration of the aggregate economic cost of regulation. Second, placing a fixed limit on the amount of resources available to an agency or programme head with a defined mission should result in more cost-effective allocation of those goods, because priorities would have to be set among possible actions. Third, the regulatory budget, like the fiscal budget, would rely more on decentralised decision-making by the programme office than on centralised regulatory reviewers, and hence place decisions closer to the real expertise in allocating scarce resources. Fourth, it would increase legislative accountability for regulatory costs.

The key problem with development of a regulatory budget is the lack of information on regulatory costs. Budgeting will require a consistent and comprehensive set of estimates on the costs of new regulation. After almost two decades of effort, the United States has established a process of regulatory analysis that could form the basis for aggregate estimates of regulatory expenditures. Several accounting problems, mostly arising from difficulties in measuring indirect regulatory costs, are still troubling and will need to be answered. The regulatory budget has been under discussion in the United States for the past decade and continues to command significant interest. However, it is clear that its adoption, should it come about at all, is still some way off.

Experimentation with regulatory budgeting concepts is already underway. In an informal way, a cost ceiling was used as a benchmark for negotiation between the President and the Congress on the content of the Clean Air Act Amendments of 1990. The agreed ceiling, about \$25 billion in annual costs, served to focus the negotiations on the most highly valued alternatives and may have been responsible for some of the most innovative provisions of the Act.

A possible use of the regulatory budget is the inclusion of a “regulatory cost ceiling” in new legislation that delegates regulatory authority. Each new law would place a ceiling on the total private sector costs that agencies could impose in writing implementing regulations. Once the ceiling was reached, new regulations would require either additional legislation to raise the ceiling or offsetting changes in other regulations to stay within the ceiling. This system would increase the accountability of the legislature and provide agencies with incentives to produce regulations that produce benefits at the least possible cost. The long-term goal is to develop a management or budgeting system that treats fiscal and regulatory expenditures in an equal manner, since both ultimately are diverted from private use. Integrating the fiscal budget with the regulatory budget - creating a “superbudget” that measures the full cost of government action - appears to be the logical final step.

Source: This discussion is adapted from John F. Morrall III (1993), *Controlling Regulatory Costs: The Use of Regulatory Budgeting*, OECD Occasional Papers in Public Management and from the *Budget of the United States Government*, Fiscal Year 1993, “Reforming Regulation and Managing Risk Reduction”, Chapter 17.

Uneven application of RIA has contributed to wide variance in the quality of federal regulations. As previously noted, OMB's 1998 report to Congress on the costs and benefits of economic and social regulations⁸² concludes that the annual benefits of regulations in force exceeds their costs (though there is considerable uncertainty in the estimates, since net benefits could range from \$34 billion to \$3.3 trillion). But the benefit/cost ratios for regulations differ markedly. As noted, more than half of the federal government's regulations fail a strict benefit-cost test, using the government's own estimates.⁸³ Hahn's analysis of agency RIAs showed a net benefit for 92 health, safety and environment regulations of \$280 billion, but suggested that net benefits could be increased by \$115 billion by eliminating those rules that failed the benefit/cost test. While regulatory quality appears high in many areas, it appears that RIA has had limited success in preventing poor quality regulation, notwithstanding the considerable experience with the tool in the United States and the significant amount of resources devoted to it.

Assessment against best practices

Maximise political commitment to RIA. The United States scores well here. Political commitment to RIA has come from the highest political level in the United States. The obligation to carry out RIA has, since its inception in 1981, been through executive orders. Moreover, each president since 1981 has issued his own revision of RIA, ensuring that the commitment to RIA has been reaffirmed by the current presidency. The support of Congress in promoting RIA has been tentative. Some laws prohibit the use of benefit-cost analysis to make policy decisions. It was only with the passage of the Unfunded Mandates Reform Act in 1995 that there was a government-wide legal requirement for RIA, albeit one that is weaker than the executive order.

Allocate responsibilities for RIA carefully. Experiences in OECD countries show no exception to the rule that RIA will fail if left entirely to regulators, but will also fail if it is too centralised.⁸⁴ To ensure "ownership" by the regulators while at the same time establishing quality control and consistency, responsibilities should be shared between regulators and a central quality control unit. The US approach is an international benchmark in this regard. The United States has established clear responsibility for regulators to conduct RIA in the first instance and a strong role for a central review authority and quality control. Moreover, the authority (OMB) is located within the Executive Office of the President and is functionally close to the budgeting authority. The clarity of its mission, its specialised and expert staff, and its location within central management bodies provides OMB with considerable ability to exercise quality control over RIA.

Train the regulators. OMB has published detailed guidance on conducting RIA.⁸⁵ The document sets out the objectives of RIA under executive order 12866 as well as methodological guidance on issues such as discount rates and valuation of human life. However, written guidance is not supported by training for regulators in using RIA, or in related topics such as assessing regulatory alternatives. This is an area where US RIA policy could learn from other countries such as Canada. OMB in 1998 recognised the need to expand training and technical assistance for agencies in improving RIA quality.⁸⁶

Use a consistent but flexible analytical method. In mandating benefit-cost analysis as the preferred method for RIA, the United States government carries out the most rigorous and far-reaching regulatory analysis of any OECD country. Yet it has proceeded pragmatically in expanding its use across the government. In practice, regulators need flexibility in conducting useful and feasible analyses. OMB's 1996 RIA guidance document states:

This document is not in the form of a mechanistic blueprint, for a good economic analysis cannot be written according to a formula. Competent professional judgement is indispensable for the preparation of a high-quality analysis. Different regulations may call for very different emphases in analysis. For one proposed regulation, the crucial issue may be the question of whether a market failure exists, and much of the analysis may need to be devoted to that key question. In another case, the existence of a market failure may be obvious from the outset, but extensive analysis might be necessary to estimate the magnitude of benefits to be expected from proposed regulatory alternatives.

Flexibility does not mean, however, that regulators should be able to escape rigorous analysis. Emerging inconsistencies in the methodologies required for RIA are a matter for concern. While the executive order imposes the benefit-cost principle, the Unfunded Mandates Reform Act requires cost effectiveness analysis, and SBREFA requires a partial analysis of effects on one group of economic actors. The existence of parallel and different requirements is not necessarily a danger, since several methods are complementary to good decision-making, but the potential for conflict between implicit principles will have to be carefully managed to ensure that the core benefit-cost principle is not undermined.

Develop and implement data collection strategies. Lack of information is a key reason for quality problems in RIA. Development of innovative and more cost-effective data collection strategies could play an important role in improving analytical quality. Like other OECD countries, the United States ranks low in this RIA element. OMB has not provided guidance to agencies on the development and implementation of data collection strategies. This seems to be an area worthy of consideration as a “next step” in refining RIA processes.

Target RIA efforts. RIA resources should be targeted to regulations where impacts are largest, and where prospects are best for altering outcomes. The amount of time and effort spent on regulatory analysis should be commensurate with the improvement in the regulation that the analysis is expected to provide.⁸⁷ US RIA efforts rate relatively well according to this criterion, although the scope of coverage is still patchy. Formal RIA is targeted toward “major” or “significant” regulations. “Major” regulations were defined in 1981 as those imposing annual costs exceeding US\$100 million, likely to impose major increases in costs for a specific sector or region, or have significant adverse effects on competition, employment, investment, productivity or innovation. The executive order distinguishes between “economically significant” regulations and “significant” regulations, and requires a full cost/benefit analysis for the former.

The degree of targeting has varied over time. During the Bush Administration, two changes significantly increased the number of rules subject to RIA. In 1991, OMB extended the impact assessment requirement by ordering that analyses be conducted on all “significant” rules, while in 1992, President Bush further extended the requirement by directing agencies to estimate the likely costs and benefits of all proposed legislation within their jurisdictions. The approach to RIA became more selective under the Clinton Administration and, as noted above, the number of rules reviewed by OMB in 1996 was less than one quarter of the average for the years 1984 - 1993. Although OMB reviewed several hundred final regulations, only 41 final rules met the definition of economically significant regulations in the year to 31 March 1997, and only 33 in the year to March 1998, thereby qualifying for a full benefit/cost analysis. This was less than one per cent of the final regulations published in 1998, but OMB stated that the 33 regulations accounted for the “vast majority of the costs and benefits” of new regulations.⁸⁸

While these changes presumably represent differing views over time on the desirable degree of targeting, three significant concerns exist regarding the limited “reach” of RIA requirements. First, some major statutes specifically exclude the consideration of economic costs by rulemaking agencies in

particular areas. Either RIA will not be conducted in these cases or, when conducted, regulators are effectively prohibited from using their conclusions in determining policy. Passage of the Unfunded Mandates Reform Act will not alter this situation. The second concern is that RIA is not usually done for proposed legislation. This is at variance with international practice, since at least 15 OECD countries focus RIA on legislation, and allows many important regulatory decisions to escape entirely from the discipline of impact analysis. Third, the executive orders requiring RIA do not apply to a large group of independent regulatory agencies. Thus, a class of important regulations are effectively exempt from RIA requirements because of the legal status of their sponsoring agencies, rather than their intrinsic importance.

Integrate RIA with the policy-making process, beginning as early as possible. Integration of RIA into the policy process is a strong element in the United States, compared to many countries where RIA is prepared too late, after decisions are taken. US RIA procedures require that RIA for both proposed and final rules be released for public consultation, ensuring that agencies are accountable for the quality and relevance of RIA throughout the decision process. OMB has recently attempted to become involved with agencies at an earlier stage in rulemaking to improve RIA quality and reduce conflict at the formal review stage. It can also be argued that the considerable exposure of US rules to legal challenge in the courts favours the effective integration of RIA with the policy process. While the standard of RIA itself is not justiciable, RIA can be used as evidence. This creates incentives for agencies to ensure that decisions taken on rules are supported by the results of RIA.

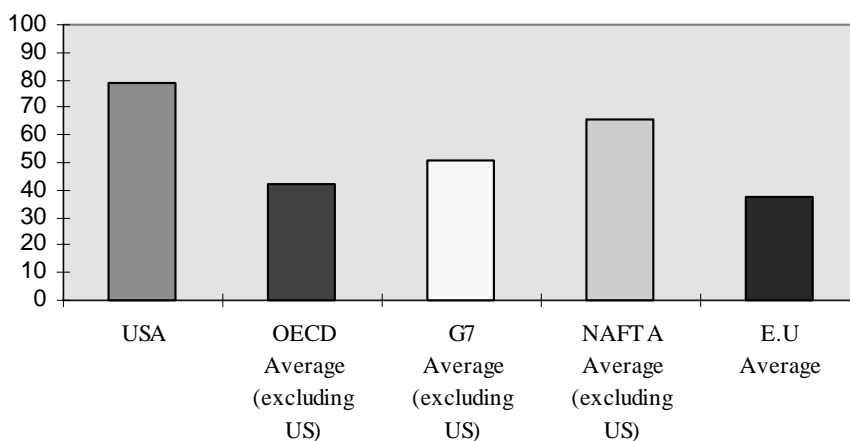
Involve the public extensively. The assumptions and data used in RIA can be improved if they are tested through public disclosure and consultation. Only a minority of OECD countries do this. RIA in the United States, by contrast, is fully integrated into the public consultation process, and provides a good benchmark for other countries. RIA are required to be released to the public at both proposed and final stages as part of the “notice and comment” process that allows all interested members of the public to comment on the assumptions and results of the impact analysis.

Use of risk assessment. A discussion of RIA in the United States would be incomplete without noting the key role of quantitative risk assessment. The United States is rare among OECD countries in making extensive use of various forms of risk analysis (including risk-risk analysis - see Box 10) as an input into benefits assessment. Fewer than 10 OECD countries use risk assessment systematically, and of these the US federal government is the most systematic consumer of risk information in setting health and safety standards.

Quantitative Risk Assessment (QRA) typically forms the basis for regulation in the health, safety and environment areas - among the most important and fastest growing areas of regulatory activity. The first formal use of QRA occurred in the early 1970s, when the Food and Drug Administration used QRA to determine the need for regulation of various drug residues with carcinogenic potential in food producing animals. Since 1981, OMB has encouraged the use of QRA to calculate the benefits of all risk reducing regulations. OMB stated that, “For government to carry out its risk-management responsibilities, there must be extensive investment in the careful assessment and quantification of risks”⁸⁹. The courts have also supported the use of risk assessment as a way of defining and limiting the discretion of agencies in regulating risk.

Box 9. The formal scope and breadth of the RIA system

This indicator looks at several aspects of the use of RIA, and ranks more highly those programmes where RIA is applied both to legislation and lower-level regulations, where independent controls on the quality of analysis are in place, and where competition and trade impacts are identified. The United States receives the highest ranking among the OECD countries on this criterion, although some elements of the RIA process, such as its applicability to legislation, are new and the quality of application shows continuing problems.



Source: OECD Public Management Service.

However, laws are highly inconsistent about how risks are to be regulated and hence agency practices vary considerably. One fundamental problem is that, as with benefit-cost analysis, a number of important statutes prohibit the use of risk assessment. In some cases this is due to the statutes dating from periods in which detection techniques were much less advanced than today: The recently repealed “Delaney Clause” for pesticides, which prohibited any trace of a potentially carcinogenic pesticide in food items, had become widely recognised by regulators as an impediment to the competent management of such risks as the threshold of detection of such substances fell precipitously over past decades. It must be noted, however, that similar Delaney clauses for food additives, and cosmetics remain on the books.

Even in the absence of legislative limitations, agencies may adopt very different benchmarks as to what constitutes an “acceptable” risk or an acceptable mandated cost of risk reduction. For example, regulators often use worst-case assumptions so as to build a safety margin into the regulatory decision. Done systematically, this practice can severely distort regulatory activities. OMB has summarised the problem thus: “The continued reliance on conservative (worst case) assumptions distorts risk assessment, yielding estimates that may overstate likely risks by several orders of magnitude...Conservatism in risk assessment distorts the regulatory priorities of the Federal Government, directing societal resources to reduce what are often trivial carcinogenic risks while failing to address more substantial threats to life and health”.⁹⁰

Box 10. Using risk-risk analysis: when does a regulation really save lives?

Risk-risk analysis is a variant of risk analysis which looks beyond the direct impacts of a regulation on risk. Its starting point is the question of whether a regulation designed to reduce one risk would also have identifiable effects on other risks. Risk-risk analysis has arisen from concerns that some regulation has actually increased, rather than reduced, total risks due to perverse indirect effects outweighing the direct risk reductions which initially motivated the regulation.

Two major mechanisms by which other risks can be increased exist. Firstly, the regulation may lead to a risk trade off in terms of a behavioural response. Regulations which restrict or discourage the consumption of one risky substance may lead to consumers substituting another which has its own, possibly greater risks. For example, regulation of artificial sweeteners may lead to increased consumption of sugar, which may have greater risks in terms of heart disease than the risks associated with the artificial sweeteners.

Secondly, actions taken to reduce one risk can simultaneously increase another, even without behavioural change. For example, chlorinating drinking water reduces the risk of bacteria borne illnesses but may slightly increase cancer risks. Similarly, switching to lead-free petrol reduces the developmental problems of high blood lead levels in children but may also increase cancer risk due to increased exposures to benzene.

A variant of risk-risk analysis considers the impact of income on health. Studies show that as income declines, mortality rates increase, with one widely cited study indicating that each \$12 million (1991 prices) reduction in aggregate income costs a statistical life. Thus, every regulatory expenditure of this amount may cost a statistical life. This form of analysis has received some prominence in the United States.

Source: Viscusi, W.K., "Improving the Analytical Basis for Decision-making" in *Regulatory Impact Analysis: Best Practices in OECD Countries*, Paris, OECD, 1997, pp. 200-204.

A detailed analysis of the inclusion of several mutually reinforcing "safety margins" in risk assessment was contained in a report commissioned by the Department of Energy in 1993⁹¹. It identified ten key policy assumptions, each widely used in risk assessment, each of which introduced a conservative bias into the results. The accumulation of these biases can lead to policy outcomes that are inconsistent with each other and with cost-effective approaches to risk management. A frequently cited example is the pursuit of clean-ups of toxic sites under the 1980 "Superfund" legislation, where critics argue that the high cost of conducting clean-ups to reduce risks to unnecessarily low levels has meant that only a small minority of identified sites have received any remedial action at all.

An additional issue is the often large degree of uncertainty attached to risk calculations, in terms of both the calculation of the initial risk and the productivity of measures that can be taken to ameliorate it. Again, different approaches are likely to be taken in dealing with this uncertainty in the absence of clear guidance.

For these and other reasons, there is huge inconsistency in risk management across the federal government. As noted earlier, federal health and safety regulations show an extremely wide variability in the costs per life saved — from thousands to billions of dollars. The highest costs are associated with regulations aimed at low-probability cancer risks resulting from occupational and environmental exposure. This enormous variance in the cost-effectiveness of various regulations has suggested to OMB that "aggregate risk mortality would be substantially reduced at considerably lower cost by shifting the Federal government's regulatory focus away from relatively small...cancer threats toward other health risks and causes of injury."

Initiatives have been taken in recent years to improve and standardise risk assessment techniques. In 1991, the White House Office of Science and Technology Policy convened a number of interagency groups to develop guidelines for agencies to use in conducting risk assessments. The National Academy of Sciences has also conducted a review of risk assessment. While risk assessment remains a highly imperfect tool, and one whose utility in policy-making continues to be questioned in some quarters, the United States is in the forefront in its adoption and refinement as a policy tool.

4. DYNAMIC CHANGE: KEEPING REGULATIONS UP TO DATE

The OECD Report on Regulatory Reform recommends that governments “review regulations systematically to ensure that they continue to meet their intended objectives efficiently and effectively.” In the United States, three key mechanisms are currently employed to review existing regulations, each authorised by executive order 12866.

The first mechanism is adoption of a general principle of review. Section 5 of the current executive order directs agencies to undertake periodic reviews of their existing “significant” regulations in order to identify modifications or repeals that would better contribute to achieving regulatory objectives, reduce burdens or better align regulation with the President’s principles and priorities as reflected in the order. No specific mechanisms are set out to ensure compliance with this requirement. However, the Performance Management and Results Act may have an impact in holding agencies accountable for compliance with this general obligation.

The second review mechanism is based in OMB. The administrator of OIRA is required to work with a regulatory working group, drawn from regulatory agency personnel, to identify regulations that require modification. The design of this mechanism scores highly in terms of consistency with OECD best practice recommendations which emphasise the need to balance regulatory agency responsibility for reform with centralised co-ordination and management by an expert reform body.

Third, the Vice President leads a programme of regulatory review. The National Performance Review set an ambitious target of a 50 per cent reduction in the number of existing regulations within five years. OMB reported in 1996⁹² that NPR efforts had led to the removal of 16 000 pages from the Code of Federal Regulations and that another 31 000 pages were modified out of a total of 86 000 pages reviewed to that point. That is, a total of about 40 per cent of the total number of pages of the Code were either removed or modified. Nonetheless, it is unclear that this review activity produced significant benefits, since cost-savings were not documented. Experiences in other countries show that it is not difficult to produce impressive results if non-monetary units such as page numbers or numbers of regulations revised are used instead of more relevant measures. For example, the General Accounting Office looked more closely at four agencies and found that these reported page reductions were almost entirely offset by new regulatory requirements in the same period.⁹³

Sunsetting and automatic review requirements are not drivers of significant review activity in the United States, except in the case of three-year sunsets on all government formalities and paperwork requirements (see below). A new requirement in the small business act requires periodic reviews every ten years for small business impacts.

4.1. *Cutting red tape*

The US federal government has an enormous appetite for information that must be fed by enterprises and citizens. This seems to be a natural result of the information age, of pressures on public administrations to target and assess programmes, and of budget cuts that have shifted costs from public to private sectors. The demand is also driven by the trend toward the use of information as a supplement or alternative to traditional forms of regulation. Indeed the magnitude of the problem is impressive. In 1996, businesses and citizens spent 6.7 billion hours filling out Federal government forms, responding to surveys, keeping records, collecting information, and dealing with other kinds of government paperwork (see Figure 1). This is equivalent to the private sector employing 3 million fulltime employees to respond to Federal information needs. Tax formalities accounted for roughly 80 per cent of the total burden.

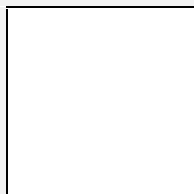
Since 1980, the United States has developed an intensive system (characteristically highly legalistic) for controlling paperwork burdens. The Paperwork Reduction Act establishes an independent reviewing agency (OIRA) and a centralised approval procedure, and offers legal protection to citizens if agencies attempt to enforce paperwork requirements that are not OIRA-approved. Granting legal authority to a central review agency to disapprove decisions by regulators — an authority that seems to be the only one of its kind in OECD countries — indicates the depth of public frustration over mandated paperwork.

Yet, the success of Federal efforts in managing the paperwork burden is mixed. OMB made significant progress in improving awareness of the costs and consequences of information collection activities, and has succeeded in slowing the growth of paperwork. Yet OIRA's efforts are overwhelmed by major new regulatory programmes that require information from the public. Hence, the programme has not been successful in reducing the burden on the public, though this was a major goal of the PRA. Between 1980 and 1996 total paperwork burden grew from 4.6 billion hours per year to 6.7 billion hours per year. This is an increase from 20 hours per citizen in 1980 to 25 hours per citizen in 1996.

The Paperwork Reduction Act. Under the Act, each federal requirement that the public or businesses collect, keep, or submit information to the government must be approved by OIRA at least once every three years. The Act gives OIRA broad authority to disapprove a paperwork requirement or order its revision if OIRA finds that (1) it does not have practical utility; (2) is not the least burdensome necessary; or (3) duplicates information otherwise available. Requests for OIRA approval are published in the Federal Register, and the public is given 30 days to provide comments. If OIRA approves a requirement, an approval number is issued that must be displayed on the form or regulation. Notably, the three year “reapproval” cycle means that consultation is conducted on an *ex post* basis, rather than simply an *ex ante* basis, as is the case with most consultation requirements.

A crucial element of the process is the self-enforcing aspect of the PRA. If a current approval number is not displayed, a member of the public cannot be penalised for refusing to keep or submit the required information. Agencies are not supposed to expend resources carrying out unproved collections of information. OMB follows up any violations with the responsible agencies, and notifies the Congress annually of such violations. There appear, however, to be a substantial number of violations. The US General Accounting Office in 1999 found 800 cases where agencies had collected information in violation of the PRA.⁹⁴

Figure 1. **Aggregate number of hours spent filling out federal government forms**⁹⁵



The upper estimates, designated by the higher line, are more accurate. The sharp increase in FY 1989 is due to a comprehensive reassessment of the tax-related compliance burdens, which found that the burdens had been substantially undercounted in earlier years. The Normalised Estimates (the upper line) adjust the previous burden estimates to incorporate the revised tax estimates.

The Information Collection Budget (ICB). A second instrument created by the PRA to control paperwork burden is the annual publication of the Information Collection Budget (ICB). The ICB is the vehicle through which OIRA, in consultation with each agency, sets annual agency goals to reduce information collection burdens. At the end of the fiscal year, OIRA reports to Congress the results for the whole government and each agency and the achievement of the goals. **Since 1980, the reduction targets have varied. In 1996** the PRA set an annual government-wide goal for the reduction of the total information collection burden of 10% during each of fiscal years 1996 and 1997 and 5% during each of fiscal years 1998 through 2001.

The ICB is built around fiscal budgeting concepts. Each agency calculates its total information collection "budget" by totalling the time required to complete all its information requests. This budgeting exercise is then used to measure progress toward reduction goals. The ICB is also an important mechanism in developing a comprehensive strategy to manage Federal information resources. The budgeting process has been considered useful because it assists agencies to evaluate broad categories of information as they relate to programme objectives, rather than as isolated collections of information. It encourages trade-offs between low and high priority information.

Recent reports have revealed some weaknesses in the ICB process. First, reduction targets have important measurement limitations. Estimating the time for an individual to collect and provide information is not simple. OIRA has not issued guidance on how to measure such burdens. Consequently, the ICB is undermined by a lack of quality and comparability of targets among agencies. For example, in 1989, IRS re-estimated the tax-related burden, tripling the government-wide burden. In 1997, the same agency concluded that tax compliance burdens may have been overstated by a factor between 3.8 and 5 and should be re-adjusted downward⁹⁶. Second, the reduction targets lack binding force.⁹⁷

New uses for information technologies. These responsibilities are closely tied to OMB's responsibility for management and co-ordination of federal information policies. An important advance in the PRA was the placement of paperwork reduction objectives squarely within a comprehensive framework for managing information resources. Paper is viewed merely as a means of handling information, and is not different in kind from other means such as electronic media. Reducing paperwork makes sense only within the broader context of information management. In a recent report, Vice President Gore stated his intent to use information technologies to create a government that works better and costs less.⁹⁸ This has been accelerated by the increasing use of the Internet which provides not only linkages and research capacities but the possibility to build user-friendly electronic one-stop shops.

Two approaches have been used by Federal agencies: use of IT to collect information more efficiently and rapidly, and use of IT to better inform the public of its rights and obligations. An example of the former concerns new ways to complete forms by "taking the paper out of paperwork". A recent initiative by the Internal Revenue Service (IRS) to offer Telefile to most single filers allows over 4 million taxpayers who used to file a paper form to file tax returns using a touch-tone phone. An example of the use of IT to provide better information and open new channels for consultation is the electronic one-stop link Business.Gov (<http://www.business.gov>). This service provides practical assistance to businesses through answers to frequently asked questions, search capacities for Federal information, browsers for Government documents, and viewing of business-related items from Federal agencies.

Simplifying permits and licenses. One of the more damaging forms of regulation is the *ex ante* licensing or permitting requirement. These kinds of regulations increase investment delays and uncertainties, have disproportionate effects on SME start-up, and are very costly for public administrations to apply. Yet they are pervasive in OECD countries. The United States has made some reforms in this area, although the potential for further gains remains substantial.

Permitting and licensing activities are split between levels of government in the United States. States use licences and permits to control the proficiency and quality of professional services (*e.g.* lawyers, doctors, accountants) and the impacts of activities at the local level (*e.g.* zoning permits). At the federal level, licences and permits are used mainly to control environmental hazards, such as from new chemicals or municipal sewerage systems, or risks arising from activities in interstate commerce, like medicines, or that involve special concerns, such as nuclear reactors. Such Federal procedures can be very complex and time consuming. They often require overview by different agencies, previous notification in the Federal Register or third party approvals⁹⁹. After issuance, the licence or permit can be challenged in court.

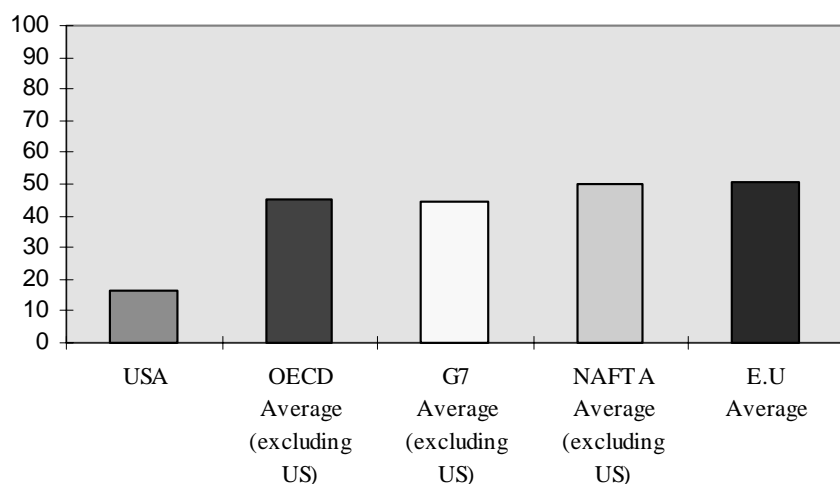
The use of licenses and permits at the federal level has evolved very slowly in the past decade. Alternatives to this 'command and control' measure are still scarce. Despite the opportunity offered by the PRA, no federal programme has concentrated on simplifying or reducing them government-wide. There may be a perception that the United States simply has fewer permits and licensing requirements, although the lack of any inventory at federal or state levels means this is difficult to assess. Some isolated steps are underway.

- In the environment area, the need for new air emission permits whenever there is a change in operations has inhibited companies from rapidly responding to changes in market demand and burdened the federal administration. A system piloted by the Environment Protection Agency will pre-approve certain operational changes over the five-year life of an air permit, which will reduce regulatory delay and permit the EPA to focus on higher priority pollution issues.¹⁰⁰
- There are also indications that some large cities are taking steps to streamline licensing to attract investment, and this is a positive dynamic.

However, if the extensive experiences of other OECD countries are a guide, this is an area where more attention in the United States could yield substantial efficiencies.

Box 11. Simplifying business licences and permits

This synthetic indicator of efforts to simplify and eliminate permits and licences ranks more highly those programmes where countries use the ‘silence is consent’ rule to speed up decision or have set up one-stop shops for businesses, where there is a complete inventory of permits and licences; and where there is a specific programme, co-ordinated with lower levels of government, to review and reduce burdens of permits and licences. Despite efforts related to the PRA, the United States ranks low on these scores relative to other OECD countries. The lack of attention to the costs of licences and permits may reflect the relatively prominent role of the states in this area, given the US federal structure. Yet, other federal states, such as Australia, have nonetheless acted at federal level to reduce the burdens of licences and permits at all levels of government.



Source: OECD Public Management Service.

5. CONCLUSIONS AND POLICY OPTIONS FOR REFORM

5.1. General assessment of strengths and weaknesses

The US government faces formidable legislative, institutional, judicial and structural constraints on good regulatory practices. Yet, by most measures, the capacities of the US federal government for assuring the quality of federal regulation are among the best in OECD countries. The synthetic qualitative indicators presented here generally place the United States in the first rank of countries. The policy framework for regulation is clear and consistent with OECD best practices. Considerable investments in institutional, analytical, and legal infrastructure for improving the quality of subordinate social and administrative regulation have produced relatively well-functioning systems in critical areas such as

establishment of a centralised and independent body to promote quality regulation, forward planning and co-ordination, systematic use of regulatory impact analysis based on benefit-cost principles, and open consultation with affected entities.

An impressive element of reform is the collective and steady effort over 20 years to improve analytical capacities and acceptance of the benefit-cost principle within regulatory agencies, under the leadership of OMB. While there are still substantial problems with adoption of regulations that do not pass the test, the level of understanding and debate about the nature and scope of regulatory impacts is unique in OECD countries. This is due almost entirely to the quantification of regulatory impacts carried out in federal regulatory bodies. Efforts underway within OMB to further improve the quality of data and analysis on the benefits and costs of regulations will permit even more sophisticated reform efforts in future. The lesson to be learned is the value of persistence and policy stability over the long term in embedding new ways of thinking into bureaucracies.

The emphasis on regulatory quality is also a strong point in the US programme. The 1980s was a period of considerable investment in reform institutions and processes, but the programme was weakened by stressing “regulatory relief” rather than benefit-cost principles aimed at maximising social welfare. The programme also relied too much on an over-centralised and confrontational process that improved the quality of individual regulations, but did little to change incentives and administrative cultures within the regulatory agencies. For example, the role of the central oversight body (OMB) was oriented toward reacting to transactions, and not to general systemic and institutional change. This lesson was learned, and a returning of the reform programme took place in the 1990s, with a targeting of OMB’s efforts and a focus on government reinvention and on results-oriented policy-making.

167. This review of regulatory reform in the United States should help dispel the myth that the United States is, on the whole, less regulated than other OECD countries. The United States appears to be different from many countries, not in the amount or detail of regulation, but in its nature and style. American regulatory culture incorporates competition principles to a greater extent than in most countries, which stems more from deep-seated habits and values than from any organised vigilance. As a result, there is less of the most damaging forms of economic regulation, but as much or more social regulation and paperwork that do not present direct barriers to competition. This pro-competitive doctrine is an asset of increasing value in a world economy characterised by globalisation, responsiveness, and rapid technological progress. The US regulatory system illustrates well the conclusion in the 1997 OECD Report on Regulatory Reform:

...economic regulations have often proven to be extremely costly and ineffective means of achieving public interest goals...In general, public policies such as protection of health, safety, and the environment are better served by using competition-neutral instruments, such as well-targeted social regulations and market incentives, to change behaviour in competitive markets.¹⁰¹

The American public is well-served by this characteristic. Yet, the key question today deals with the direction of change: Are federal regulations of higher quality than 25 years ago, that is, do they, in the aggregate, produce higher net social benefits for the American people? While no answer can be definitive, the answer is probably yes, for two reasons:

1. The enormous shift since the 1970s from anti-competitive economic regulation toward more neutral styles of social regulation has greatly improved the benefits of the regulatory system as a whole, since social regulations are much more likely to produce net benefits than do economic regulations. OMB has calculated that the total benefits of social regulation in 1998 greatly exceeded costs, while the costs of economic regulations greatly exceeded their benefits.¹⁰²
2. Controls on quality of social regulations and paperwork have steadily developed and government capacities to assure high-quality decisions are relatively strong.

This improvement is a longer-term trend, since application of quality controls can obviously vary over time. The overall quality of new federal regulations probably varies significantly, depending on political commitment and support for quality management. Yet the trend is in the right direction.

This positive trend should not induce complacency. US regulatory habits of detail, legalism, and rigidity are still dominant. There continue to be severe problems with costs and policy effectiveness in the US regulatory system. Much legislation and regulation is seriously outdated. Quality control processes are not co-ordinated, and have important gaps in the areas of primary legislation, economic regulation, and state-level regulation. Studies from different sources suggest that net social benefits for social regulations issued in recent years are positive, a significant though not a robust finding, but that many individual regulations impose costs higher than benefits. This means that aggregate costs of regulations can be substantially reduced without reducing social welfare.

Coherence and consistency, both horizontally across the US government and vertically in federal/state relations, still pose problems. The United States faces enormous difficulties in establishing consistent regulatory quality standards and controls on the sprawling regulatory apparatus of the federal government, and even more difficulty in managing coherence and complexity in federal/state interactions. There are tensions in the system between due process and flexibility, between legal clarity and innovation, and between empirical and legal/adversarial methods. An analysis of governance in the United States found difficulties with coherence to be inherent in the constitutional set-up of the American government:

*The problem of governance in the United States is mainly one of creating institutions or governing arrangements that can pursue policies of sufficient coherence, consistency, foresight, and stability that the national welfare is not sacrificed for narrow or temporary gains. The United States has difficulty in arriving at such arrangements because it must fashion them out of three substantially autonomous political institutions: Congress, the presidency, and the bureaucracy.*¹⁰³

This suggests that imperfections in the American regulatory system are rooted in the American way of governance. But reformers still have an important role: there is considerable distance to travel before these structural constraints are binding.

At the heart of the most severe regulatory problems is the quality of primary legislation. The trend toward higher quality in delegated regulation cannot be seen in the quality of primary legislation, and this limits, and threatens to reverse, the benefits to be gained from regulatory reform. More so than in other OECD countries, the United States has found it extremely difficult to develop controls on legislative quality. This is partly structural, arising from the constitutional balance of powers between the executive and the legislative. And, unlike parliamentary systems, bills originate from many sources. The result is that, perversely, there is less attention to quality of laws than to decisions authorised by the laws.

In the past, the Congress has ignored even those slight controls that it adopted for itself, though recent reforms, such as the UMRA requirement that the Congressional Budget Office estimate the costs of proposed legislation and “unfunded mandates” on state and local governments, are positive. If this is to have value, members of Congress will have to become consumers of such information. It remains to be seen how such estimates will be considered in Congressional processes, but anecdotes suggest that it has helped raise the level of debate on such costs.¹⁰⁴ Current proposals to establish a new congressional agency to study the costs and benefits of regulations could improve matters if the agency were to focus on bills and existing legislation as its top priority. Strikingly, some recent laws, such as the Clean Air Act of 1990, expressly prohibit good decision practices by regulatory agencies.

Innovation and the development of cost-effective policy approaches are often blocked by rigid legislation. "EPA is hobbled by overly prescriptive statutes that pull the agency in too many directions and permit managers too little discretion to make wise decisions. Congress should stop micro-managing EPA." concluded a recent report of the National Academy of Public Administration. A deeper problem, noted a former head of the US Environmental Agency (and as noted earlier for nursing home regulation), is that frustration with regulatory performance, perhaps justified or perhaps stemming from unrealistic expectations, can lead to a vicious cycle of controls and increased barriers to good performance:

When traced to their source, many of the more vexing problems...have their roots in the underlying statutes. Besides being prescriptive, these statutes tend to over-promise setting up expectations of absolute safety within extremely tight time frames. While this is well-intentioned, it has an undermining effect on the Agency and those who rely on it. As EPA misses one deadline after another, the courts intervene, as requested by an aggrieved party, and Congress turns the screws even tighter, further limiting the Agency's ability to respond creatively and responsibly to problems far more complex than lawmakers could have possibly envisioned.¹⁰⁵

OMB has similarly warned that, “It is our view that highly prescriptive legislation...has contributed to a regulatory system that is sometimes unmanageable or is driven by plaintiffs rather than by a rational planning process that directs the nation’s resources to the most important problems and the most cost-effective solutions.”¹⁰⁶

Without genuine progress at the legislative level in placing accountability on results and in encouraging risk-taking and policy innovation, it is doubtful that the executive branch can make substantial additional progress in the quality of subordinate regulations, or even preserve the progress that has been made. It is clear that there is no quick fix. The two most positive steps in recent years are the Performance Management and Results Act, which builds a foundation for results-oriented policies and more accountability to Congress, and the trend toward improving dialogue and consensus on innovative regulatory approaches, which experience in other countries shows is a necessary condition for building the trust that is needed if administrators are to have the flexibility to innovate and take risks.

The importance of a vigorous academic community in producing policy-relevant data to support regulatory reform should not be over-looked. The continuing efforts of researchers in American think tanks and universities have mapped the evidence of benefits from reform and posed strong challenges to the status quo. Such scholarship is, in fact, one of the most influential exports of the United States to the rest of the world.

5.2. *Policy options for consideration*

There is a large and growing volume of recommendations from many sources on ways to improve regulatory reform in the United States. Most of these consist of fine-tuning existing structures; some, such as those in the NPR, are more profound, aimed at changing the incentives and culture of regulators. This section identifies actions that, based on international consensus on good regulatory practices and on concrete experiences in other OECD countries, are likely to be particularly beneficial to improving regulatory management and reform capacities in the United States. Reforms should seek to:

- *Improve the responsiveness and quality of the national regulatory system by:*
 - *Continuing to seek means to streamline regulatory processes through the NPR process.*
 - *Strengthening quality management in the executive and legislative branches as a better substitute for some aspects of judicial review.*
 - *Reviewing current administrative law practices pertaining to regulatory development and consultation.*
 - *Better integrating numerous regulatory quality procedures such as impact analyses, review processes, and performance measurement.*
 - *Increasing the use of sunseting to ensure that regulations are kept on the books only if they are still necessary.*

Sluggishness, delay, and inefficiencies in regulatory processes will increasingly penalise the United States as the pace of globalisation and innovation steps up. New regulations that are socially beneficial should be issued faster, and existing regulations should be updated more regularly. The lack of policy responsiveness and flexibility implied by the long and cumbersome regulatory process has long been recognised. The 1993 NPR noted, for example, that a layering of procedural requirements has, cumulatively, “made the rulemaking process increasingly burdensome and rigid.”¹⁰⁷ Since 1993, the situation has worsened.

At the same time, better data is revealing substantial shortfalls in meeting benefit-cost and cost-effectiveness tests, and persistent problems with the quality of economic analysis. Although regulations that fail these tests may be adopted for good reasons such as equity or justice, there is widespread agreement that substantial gains to public welfare are possible by boosting regulatory quality as measured by those empirical methods. The answer to both problems lies in rationalising the current system rather than in adding new procedures and expanding judicial review.

The cost and length of time needed for regulatory change has imposed large hidden costs on the quality of the national regulatory system. Regulators are less willing to implement new regulatory quality procedures when it already takes so long to get regulations through the pipeline. Beneficial modifications to old regulations are less likely to be carried out. Given the enormous investment needed, regulators are less likely to innovate and take risks, since a setback can cost several years of effort. Of concern is the tendency by regulators to use policy statements, guidance, and memos to agency personal that side-step procedural requirements. While such methods can be efficient, incentives to use them as time-saving measures are likely to be perverse, and can undermine the transparency of the regulatory system.

Further, the adversarial and legalistic process for producing new regulations produces an incentive for “all or nothing” solutions that drive regulators away from the rule of reason, and limit the sensible application of rules in the field. The NPR found that “Lack of information is [a] serious problem. To some extent, this stems from the adversarial nature of the rulemaking process; in many rule-makings, regulated entities, public interest groups, and other parties are more interested in protecting their own positions than in providing useful information to the agency or finding a solution to the problem.”

Improving regulatory responsiveness while at the same time strengthening quality management will be difficult, since procedural and legal formalism is so heavily embedded in the US policy system, but this review suggests that a series of concrete steps should be considered:

- A thorough review of the Administrative Procedure Act (APA) and its current application by regulators and the courts would be an important contribution to identifying where regulatory procedures can be simplified, while maintaining transparency and full consultation. Supplements to “notice and comment” procedures that enrich dialogue and draw in a wider range of interests should be considered as part of the review of the APA, and IT approaches should be critically assessed. The UK has eased procedures to revise existing rules if the revisions improve cost-effectiveness, and perhaps similar streamlining could be considered in the United States.
- In parallel with a review of the APA, a review of all existing regulatory procedures such as impact analyses and review processes should be carried out. The current system of regulatory quality control is the sum of various piecemeal procedures that have accumulated over years. In this case, the whole is less than the sum of its parts, because scarce resources are scattered through many steps rather than targeted on the most important issues. Rationalisation of benefit-cost analysis, unfunded mandates analysis, paperwork estimates, small business analysis, environmental assessments, and other into a single integrated assessment will produce better results at lower cost, better target real problems, improve consistency of treatment, and avoid duplication of effort. Compliance with these quality processes should also be linked to the Performance Management and Results Act. One performance measure, for example, could be the increase in the net social benefits produced by the agency each year, as estimated in *ex ante* impact analysis, though this will necessitate strong quality control to offset incentives to overstate net benefits. Targeting of OMB review to only major reviews eliminated a step for many regulations, but probably has had only minor effects on the overall speed of rulemaking.
- Strengthening management and quality disciplines in the administration or in the Congress — in OMB, CBO, or a new congressional agency — should be considered as a lower-cost substitute to judicial review of some aspects of regulatory quality. There is little doubt that litigation rights, whatever their benefits, slow change and innovation in the regulatory system. Proposals to subject regulatory analysis to judicial review could worsen regulatory responsiveness by increasing the scope for legal uncertainties and delays. The 1996 Small Business Regulatory Enforcement Fairness Act allows judicial review of agency studies of small business impacts; several cases have been filed. A less costly approach would have been to establish a stronger watchdog in the administration to resolve problems before regulations are issued. At the same time, stronger internal controls and filters will help to increase the percentage of regulations that meet the benefit-cost test and increase regulatory net benefits. For this reason, Hahn and Breyer have also recommended that the role and capacities of OMB and CBO be upgraded, but they did not link this to reduced judicial review.¹⁰⁸ Too, with the Results Act, the role of OMB should focus more on the performance of regulators rather than the quality of individual rules.

- The role of sunseting and systematic evaluation of regulations, rarely used in the United States, could be important in keeping regulations up to date, but will have real value only if procedures to revise existing rules are streamlined at the same time. Evaluation and sunseting in other countries have often become rubber-stamping exercises, and this is a higher risk in the United States, given the procedural costs of making even minor changes.
- Regulatory negotiations and consensus-building processes such as those promoted by the NPR offer the best chance for real change. They will require cultural shifts in the administration, and a more supportive legal environment for dialogue and innovation.
- Regulatory benefits should be increased by developing methods to improve government-wide priority-setting.

The single regulatory reform measure likely to produce the most substantial gains in social welfare is improvement of priority-setting mechanisms across the government. The importance of allocative efficiency across the range of regulatory activities has been neglected in attempts to increase the static efficiency of individual rules. The finding by Hahn that just two federal rules out of 106 produced over 70 per cent of net regulatory benefits suggests the magnitude of the potential gains from better priority setting. No OECD country has solved this problem. To the extent that it can develop methods for comprehensive regulatory priority-setting, the United States has an opportunity to lead the way for other OECD countries in the next major phase of regulatory reform.

Several attempts have been made to improve priority-setting within legislative constraints. Forward planning through the Regulatory Plan has been useful for other reasons, but has been ineffective in forcing trade-offs between regulatory agencies, though this was one of its original purposes. The regulatory budget concept is attractive from a theoretic view, but its methodological and political difficulties have prevented its implementation. Current efforts by OMB, required by law, to improve global estimates of costs and benefits of federal regulation could establish a firmer methodological basis for regulatory budgeting. Others have recommended that the regulatory budget be applied only to new regulatory costs,¹⁰⁹ a partial solution that may be more practical than a global budget constraint. The NPR recommended that similar risks be ranked and that priorities be set across agencies, but nothing has come of the recommendation. It is possible that the Performance Management and Results Act is a step toward a priority-setting mechanism through which fiscal budgeting decisions are linked to the ability of regulatory programs to deliver more per dollar expended. Certainly, this is the expectation of some members of Congress.¹¹⁰

- ***Expand the value, speed and scope of review of primary legislation and major regulations by launching a structured process of rolling reviews, reviewing policy areas rather than individual rules, and experimenting with use of advisory bodies for the reviews.***

A strong point of the US system is the central review mechanism within OMB for new regulations and formalities. Quality procedures have been integrated into the regulatory culture of the public service. Yet the current system is very weak with respect to systematic review of the vast body of existing laws and other regulations. It looks forward, but not back. For example, while reviews by the regulators themselves in 1993-1994 eliminated many pages of regulations, the actual benefits in terms of cost-savings or policy effectiveness were not well documented, and are unlikely to be significant since most changes were marginal.

A high priority should be placed on developing better evaluation and review procedures for major regulations, and for legislation in particular. As noted, American laws are likely to be lower quality than subordinate regulations, due to the imbalance in quality controls between the two instruments and the lack of any consistent evaluation of the performance of existing laws. This has substantial negative downstream effects on the quality of policy implementation and policy outcomes. This review has documented in particular the negative effects of current styles of law on innovation and experimentation by the administration.

More attention should be placed on systematic review and upgrading of laws with their subordinate regulations through a rolling review process based on a prioritisation of manageable policy areas. Policy areas subject to a high level of technological change or where regulatory failure is most costly should have highest priority. Structuring of an effective review process will be key to its results, and may require strengthening the capacities of the OMB and congressional offices such as CBO. Two approaches should be considered. First, efforts in other OECD countries show that achieving consensus in advance on a transparent and measurable set of principles for review is essential. This was seen in the current Australian regulatory review against competition principles, which includes both federal and state governments and is unprecedented in its scope. The requirement in UMRA for a cost-effectiveness test for new legislation is a good step toward consensus on results-oriented principles, but a benefit-cost test and an emphasis on innovation and experimentation will produce the best results in increasing social welfare. One purpose of the reviews should be to progressively close legislative gaps in the use of benefit-cost analysis.

Second, the reinvention principle should guide the reviews. In their peer review of this report in June 1998, other OECD countries unfavourably compared the incremental and piecemeal nature of legislative change in the United States to the greater capacity for fundamental reform often enjoyed by parliamentary governments. Similarly, current regulatory review processes in the United States are transactions-oriented rather than results-oriented. They work better in analysing individual regulations than in understanding interactions between a group of regulations affecting an economic or social sector, having a cumulative and overlapping impact, originating from different agencies or even different levels of government. Such linkages are often not analysed. US regulatory reviews seem focused on pruning each tree rather than improving the health of the forest.

The effectiveness of US regulatory review could be improved by comprehensive assessments by a high-level advisory board, commission or task force of how the regulatory framework affects an economic sector, emphasising policy effectiveness and impacts on consumer welfare as performance measures. Recommendations would include groups of reforms affecting different instruments or policies, packaged together to permit quicker regulatory improvement. In every law reviewed, emphasis should be given to encouraging innovation in approaches, with clear accountability for results, and to identifying the most efficient federal/state relationship in the policy area.

Panels of affected interests are used in the United States to comment on proposed regulations, but the United States is missing an opportunity to use such panels to evaluate and reinvent existing regulations. Setting up of advisory groups representing a good cross-section of stakeholders can gain from the experience of various OECD countries where ad hoc or standing task forces, often formed by senior business and trade union representatives, have proposed reform measures. Australia set up in 1996 the Small Business Deregulation Task Force to propose changes to reduce "the burden of paperwork and red tape on small business by 50 percent".¹¹¹ In the United Kingdom, a Better Regulation Task Force was recently established, with members drawn from big and small businesses, consumer and citizen groups, charity and voluntary sectors, trade unions and enforcers, to comprehensively review nine regulatory areas (principles of good regulation, consumer law, employment law, social services, charities and the voluntary

sector, company law and corporate governance, environmental regulation, food, and licensing). The Danish regulatory programme has gained coherence and speed from the establishment of high-level commissions and task forces. Using this approach effectively may require review and revision of the restrictive procedures in the Federal Advisory Committee Act.

An area where such an approach has been shown to be useful is in the simplification of tax-related paperwork, the largest single source of paperwork burden on enterprises in any OECD country. In the United States, tax-related paperwork burdens represent 80 per cent of the total burdens. The “Van Lunteren Commission” in the Netherlands is a model for an effective ad hoc commission in this area.

– ***Expand coverage of mandatory quality controls to economic regulation.***

As noted, economic regulation is less likely to produce net benefits than is social regulation. An ideal regulatory reform programme therefore would put stricter controls on the use of economic regulations than on social regulations. The US programme does the opposite. The independent commissions responsible for most of the economic regulations are not covered by the executive order on regulatory quality. This gap is rooted in historical and legal relations between the independent commissions and the president. The result is that these commissions provide relatively little quantitative information on the benefits and costs of their actions, and reviews by the GAO and the OMB have found that they produce no information useful for estimating aggregate costs and benefits.¹¹² Similar to the coverage of the Paperwork Reduction Act, regulatory quality controls applicable to social regulation, particularly benefit-cost analysis and consideration of alternatives, should be extended to the independent regulatory commissions, which may require law rather than executive order.

– ***Further encourage the use of cost-effective alternative policy instruments by developing operational guidance for ministries and by developing a wider range of co-operative methods.***

One of the anomalies in the American regulatory system is that positive social views toward competition have not led to a greater use of market-based approaches to problem-solving. Market approaches have been recommended for years, most recently by the Vice President’s National Performance Review. However, the US regulatory system is relatively less innovative than those in some other OECD countries. For example, ten years later there is still only one nation-wide system of marketable permits for air emissions, though the benefits of such an approach have been well-documented in other areas. Other OECD countries use taxes to restructure incentives to a much greater extent than does the United States, suggesting missed opportunities for cost-effective action. Voluntary approaches have been hampered by inflexible statutes.

The current Clinton executive order requires that analysis of alternatives be documented and subjected to public scrutiny through the RIA process to stimulate genuine comparisons of the benefits and costs of various approaches. UMRA requires agencies to certify that they are choosing the most cost-effective approach. These are good practices of value to other OECD countries. However, they do not seem sufficient in themselves to stimulate innovation, since there are powerful countervailing pressures to risk-taking and co-operation.

One of these pressures is the legalistic habits that, while intended to promote fairness and transparency, lead almost always to traditional command-and-control means. This is reinforced by traditionally weak accountability mechanisms for the performance of regulatory programmes, which have emphasised inputs such as inspections and rules, rather than outcomes in terms of results and costs. Incentives within the bureaucracy have been deeply conservative and risk-avoiding. Finally, the traditional adversarialism of decision-making emphasises an all or nothing approach.

There has been progress in recent years. The Performance Management and Results Act should weaken incentives to avoid risk-taking at any cost to programme results, and measures of the use of innovative approaches could be built into the performance measures for each regulatory agency. The focus on consensus-building is another positive step, though current approaches seem to be hampered by legal constraints and formalistic habits. A good practice that should be considered government-wide, and by other OECD countries, is to build responsibility for innovation into the bureaucracy through processes such as the 1998 ECOS-EPA Agreement, in which there is a legitimate and transparent channel for new ideas to be considered.

As recognised by the NPR in 1993, policy makers are likely to require assistance in the identification and development of suitable alternative policy tools. Operational guidance on the characteristics and use of alternative approaches should be developed for use by the line ministries. Such guidance has been useful in several countries such as Australia and Canada. General rules, called the Open Market Trading Programme, for local air-pollution-permit trading that were proposed by the EPA to speed up use of trading by the states is a good step that should be considered for other innovative approaches.

An important lesson for the United States from other countries is the value in terms of flexibility, cost-effectiveness, and responsiveness of more co-operative approaches to problem solving. Already, agencies in the United States are experimenting with such approaches. Negotiated rulemaking is one such effort, but the current approach still relies very heavily on traditional regulatory processes, and its value is not yet proven. It may be that covenants as used in many European countries are an example of a different approach. Continued leadership from the centre to encourage risk-taking and experimentation, and evaluation will be needed to promote efforts to inject a degree of co-operation into adversarial systems.

- *Develop a stronger role for the central reform authority in benchmarking analytical quality, and in facilitating and providing practical guidance to regulatory agencies.*

As noted above, stronger internal controls on regulatory quality, perhaps in OMB, could boost the rate of compliance with the benefit-cost principle, and is highly preferable to judicial review as a method of quality management. Increased attention in OMB to improving the methods and comparability of analysis, now underway in response to a legal mandate, could assist in establishing clearer benchmarks of acceptable analysis that would be useful in filtering out poor regulations. In particular, more investment in evaluation of regulatory impacts after implementation would provide useful feedback in gauging the accuracy of ex ante RIAs, and could support the refining of the RIA programme to reduce any systematic biases.

OMB has recently moved to develop more co-operative relationships with regulatory agencies and to become involved at earlier stages in rule-making processes. It proposed in 1998 to raise the quality of RIA by promoting better use of Best Practices guidelines, and by offering technical outreach and training sessions.¹¹³ This is consistent with changes in a number of countries with extensive experience with reform, including the Netherlands, Canada and Australia, where central reform bodies have moved from adversarial toward more supportive approaches to regulators. However, OMB has not emphasised the provision of tools to assist agencies to regulate better. Such tools include practical guidance on issues such as regulatory alternatives, principles of good regulation and regulatory impact assessment, backed by extensive training programmes to ensure skills acquisition by regulators. Initiatives of this sort could help build on the cultural changes among regulators that previous OMB reform efforts have produced, by giving regulators better tools for reinventing regulation. It is also useful in the context of a more results-oriented environment in which regulators become problem-solvers rather than production lines for legal texts.

- ***Encourage entrepreneurialism by streamlining permits and licenses at the federal level, by co-ordinating with the states on review and streamlining of permits and licenses, and by building more complete information systems for enterprises.***

Though *ex ante* permits and licenses can be among the most damaging of government formalities with respect to business start-ups and among the most costly regulations to administer, current efforts in the United States place too little focus on ensuring that such requirements are the minimum necessary to achieve policy objectives. This is probably due to the fact that most such requirements take place at state and local levels. Yet new ideas — such as the move to a “supply model” in Germany that offers various choices to investors, depending on the degree of risk they wish to accept¹¹⁴ — are being developed and implemented in many OECD countries, and could be useful in the United States.

One problem is that there is no general overview of the use of licensing. At the federal level, the Administration should consider having OIRA lead an interagency programme to “re-engineer” important licences and permits. The thrust of this programme could be to reduce the most frequently used and costly licences and permits, and co-ordinate between federal and state authorities. An important criterion would be to minimise costs collectively as well as individually (*i.e.* reducing overlaps, increasing information collection synergies between agencies).

The federal government should consider means of promoting the streamlining of permits, licenses, and other government formalities carried out at state and local levels. For example, it may wish to encourage adoption of paperwork reduction acts at state levels. A programme of regulatory benchmarking across states may help stimulate political interest in improving the business environment, as it has in Australia and Mexico. Also, Australian State governments have agreed to adopt parallel regulation in many areas where divergent regulations would impose extra costs. The federal government has been a key facilitator of this process in Australia.

Finally, information technology has been under-used in this area in the United States. Development of a user-friendly public registry and inventory of formalities on the Internet could provide useful information on approved information collections, such as a plain language list of the items would be available: all the information elements required, the statutory time responses of the authorities, if the ‘consent is silence’ rule applies, the means or procedure to present (or maintain) it an electronic copy of the forms, etc. This central data base could evolve progressively into becoming an electronic one-stop shop where the formalities could be directly inputted and sent to the agencies.

5.3. *Managing regulatory reform*

The most important determinant of the scope and pace of further reform is the attitude of the Congress. Congressional incentives to relinquish control over *how* policies are carried out in return for more accountability for policy results are not strong, though they are improving. In the end, it will be the management of a more results-oriented relationship between the executive and the legislative that will determine the scope and pace of regulatory reform in the United States.

While the US public debate over regulatory reform is among the most well-informed and transparent in OECD countries, there is still too little information on the results of reform strategies, including their effects on programme effectiveness, costs, economic performance, and distribution of gains and losses. Yet this information is critical if reform is to enjoy support from citizens who place high value on safety, health, environmental quality, and other values promoted by regulation. At this juncture, it seems that fears about the effects of reform on levels of protection have not been borne out, but continued reform will proceed faster and more deeply if reformers take concrete steps to demonstrate that protection has been maintained. Evaluation of the impacts of reform and communication with the public and all major stakeholders with respect to the short and long-term effects of action and non-action, and on the distribution of costs and benefits, will be increasingly important to further progress.

NOTES

1. A summary of these estimates is given in US Office of Information and Regulatory Affairs, Office of Management and Budget (1997), Report to Congress on the Costs and Benefits of Federal Regulations, September 30.
2. US Office of Information and Regulatory Affairs, OMB (1994), Report to the President on Executive Order No. 12866, 1 May.
3. President Bill Clinton (1993), Executive Order No. 12866, Regulatory Planning and Review, 30 September.
4. This characteristic has deep roots in American history. Perhaps the most important condition for the economic development of the United States over the past 150 years “was the social creed of untrammelled freedom for the producer, which was used to legitimise the physical exploitation of the continental domain after 1865,” remarked a noted historian. Greenleaf, William (ed) (1968), *American Economic Development Since 1860* (University of South Carolina Press), p. 1.
5. Noll, Roger and Bruce Owen (1983), *The Political Economy of Deregulation: Interest Groups in the Regulatory Process*, American Enterprise Institute, Washington, D.C., pp. 26-27.
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14. US Office of Information and Regulatory Affairs, Office of Management and Budget (1997), Report to Congress on the Costs and Benefits of Federal Regulations, September 30, p. 27.

15. See, among others, Hazilla, Michael and Raymond Kopp (1990), "Social Cost of Environmental Quality Regulations: A General Equilibrium Analysis," *Journal of Political Economy*, Vol. 98, No. 4; and Jorgensen, W. Dale and Peter J. Wilcoxon (1990), "Environmental Regulation and U.S. Economic Growth," *Rand Journal of Economics*, Vol 21, No. 2.
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26. House Concurrent Resolution 448, 94 Stat. 3680, November 20, 1980.
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28. Data from the Washington University Center for the Study of American Business.
29. One study found that 0.44 percent, or 31 percent, of the decline in U.S. manufacturing productivity in the 1970s was due to these kinds of regulation. See Gray, W. (1987), "The Cost of Regulation: OSHA, EPA and the Productivity Slowdown," *American Economic Review*, December, 77(5), pp. 998-1006. See also Gray, W. (1991), "The Impact of OSHA and EPA Regulation on Productivity Growth," *Journal of Regulation and Social Costs*, June, 1(3), pp. 25-47.
30. President Ronald Reagan, "The Regulatory Message of the President," Regulatory Program, April 1, 1988 - March 31, 1989, p. vii.
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32. OECD (1995), "Recommendation of the Council of the OECD on Improving the Quality of Government Regulation," Paris.
33. Presidential Executive Order 12866, Regulatory Planning and Review, September 30, 1993.
34. The indicators used here are part of a dataset under construction as a contribution to the OECD Secretariat's horizontal work programme on regulatory reform. They are based in part on a survey of all OECD countries carried out in March-April 1998.

35. Deighton-Smith, Rex (1997), *Regulatory Impact Analysis: Best Practices in OECD Countries*, OECD, Paris, p. 221.
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