

## COUNTING REGULATORY BENEFITS AND COSTS: LESSONS FOR THE US AND EUROPE

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### ABSTRACT

This paper reviews the US and European experiences with regulatory oversight and the use of formal tools to analyze regulation. We conclude that the US and Europe have made some progress in improving regulatory analysis and oversight, but they can do much more.

We offer six recommendations for improving the quality and transparency of regulatory oversight and analysis: three recommendations for the United States and three for Europe. For the US, we suggest that: 1) The Office of Management and Budget (OMB) apply its in-house expertise to evaluate the costs and benefits of regulations; 2) Congress pass a law requiring that *all* federal regulatory agencies submit annual cost and benefit estimates of major regulations to OMB; and 3) OMB issue a scorecard assessing the overall quality of regulation and ask the agencies to complete a scorecard for each major regulation.

For Europe, we suggest that: 1) The European Union (EU) pass a directive specifying that the primary objective of regulation is to maximize net benefits; 2) The EU create a strong centralized regulatory oversight unit to help evaluate regulatory proposals; and 3) The EU, as well as each member state, create a structure that is balanced, which promotes efficient regulation and discourages inefficient or ineffective regulation.

### INTRODUCTION

The United States devotes considerable resources to developing information on the costs and benefits of regulation, especially at the federal level.<sup>1</sup> It is by no means, however, the only country interested in developing more effective

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<sup>1</sup> Although costs and benefits should be quantified and monetized to the extent reasonable, qualitative descriptions of costs and benefits are acceptable when quantifying them is not possible. Quantifiable net benefits should be used in conjunction with nonquantifiable benefits and costs to reach a decision. See, e.g., See Kenneth Arrow et al., *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation*:

and efficient regulation. Because regulation can have a dramatic impact on both consumer welfare and the overall economy, several countries have developed procedures for assessing its impact. Regulatory oversight and assessment procedures vary both within countries as well as across countries.<sup>2</sup>

In this paper, we provide an overview of some mechanisms used for regulatory assessment and oversight in the US and in Europe. Our interest is in developing some general recommendations for improving regulatory oversight in both the US and Europe. We think that our recommendations will be particularly useful for the upcoming Lisbon Agenda.<sup>3</sup>

Section I of the paper provides an overview of US oversight mechanisms and assesses a series of government reports on the costs and benefits of federal regulation. Section II provides a summary of the European experience with regulatory oversight and regulatory impact analysis. Some recommendations for reforming the US and European approaches are outlined in Section III. The final section contains conclusions and recommendations.

## I. US EXPERIENCE WITH REGULATORY OVERSIGHT

Since 1980, all three branches of American government have shown increased interest in cost-benefit balancing.<sup>4</sup> Our emphasis here is on the actions of the executive branch, which has had a longstanding interest in cost-benefit balancing, an interest that cuts across partisan lines.

In 1971, President Nixon introduced the Quality of Life review process, which required agencies to consider various regulatory alternatives and costs when developing significant regulations. President Carter introduced a similar process with his Regulatory Analysis Review Group, designed to conduct inter-agency analyses of proposed regulations that were significant. But the decisive step came under President Reagan, with the formal creation of a mechanism for OMB review of major regulations. OMB is the executive branch agency created in 1970 to assist the President in the development and implementation of budget, program, management and regulatory policies.<sup>5</sup>

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A Statement of Principles (1986), available at [http://aei.brookings.org/publications/books/benefit\\_cost\\_analysis.pdf](http://aei.brookings.org/publications/books/benefit_cost_analysis.pdf). for appropriate use of cost-benefit analysis in federal regulations. [hereinafter *Benefit-Cost Principles*].

<sup>2</sup> For a discussion of the variations within and across countries, see Robert W. Hahn, *Reviving Regulatory Reform: A Global Perspective* (AEI-Brookings Joint Center for Regulatory Studies, 2000).

<sup>3</sup> The European Council will conduct a Mid-Term Review of the Lisbon Agenda in 2005. In Lisbon in 2000, every EU member state made a commitment to economic reform. One objective was to surpass US job-creation and productivity within ten years, with a goal of 20 million new jobs by creating strong, flexible, and open markets. See Lisbon Strategy, available at [http://europa.eu.int/comm/lisbon\\_strategy/index\\_en.html](http://europa.eu.int/comm/lisbon_strategy/index_en.html).

<sup>4</sup> This section draws upon Robert Hahn and Cass Sunstein, 'A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost Benefit Analysis', 150 U. Penn. L. Rev. (2002) 1489. [hereinafter *A New Executive Order*]

<sup>5</sup> For the history, mission and structure of the OMB, see OMB's website at <http://www.whitehouse.gov/omb/organization/index.html>.

The most important innovations in President Reagan's Executive Order 12,291 were: (1) a set of substantive principles for all agencies to follow, 'to the extent permitted by law', including a commitment to cost-benefit analysis; (2) a requirement that a regulatory impact analysis, including cost-benefit analysis, accompany all 'major' regulations; and (3) a formal mechanism for OMB oversight, with a general understanding that OMB had some control over what agencies would actually do.

Executive Order 12,291 proved extremely controversial. Nonetheless, President Reagan expanded on the basic idea four years later with Executive Order 12,498. That order established a requirement that agencies submit 'annual regulatory plans' to OMB for review. The result was an annual publication, the Regulatory Program of the United States, which contained a discussion of all proposed actions that might be either costly or controversial. Executive Order 12,498 served to increase the authority of agency heads over their staffs, by exposing proposals to top-level review at an early stage. But it also increased the authority of OMB, by allowing OMB supervision over basic plans, and by making it hard for agencies to proceed without OMB pre-clearance.

Under the first President Bush, the principal innovation was the Council on Competitiveness, chaired by the Vice President. The Council engaged in occasional review of agency regulations, operating as a kind of supervisor of OMB itself. It also set out a number of principles and proposals for regulatory reform. In essence, however, the Bush Administration followed the basic approach of its predecessor, with OMB review remaining under the two Reagan executive orders.

Cost-benefit balancing had been highly controversial when conducted by Republican administrations. For this reason, it was uncertain whether President Clinton would allow it to continue to play a role within the executive branch. But in a significant step, President Clinton endorsed the essential features of the Reagan-Bush orders in his Executive Order 12,866.<sup>6</sup> The crucial point about Clinton's order is that it accepted the basic commitments of the two Reagan-Bush orders, by requiring agencies to assess both costs and benefits and to proceed only when the latter justified the former.

At the same time, President Clinton offered several changes to the Reagan-Bush processes, mainly attempting to create assurances against the fear of industry capture of the system of review. First, he attempted to diminish public concerns about interest-group power over regulation, by providing a process to resolve conflicts and procedures for greater openness.<sup>7</sup> Second, he included references to 'equity' and to qualitative as well as quantitative factors, evidently so as to ensure that agencies could have more flexibility in

<sup>6</sup> See Exec. Order No. 12,866, 3 C.F.R. § 638 (1994).

<sup>7</sup> Id.

decision-making.<sup>8</sup> Third, President Clinton moved, in a modest but important way, toward including independent agencies within the executive orders. He did so by requiring the participation of the independent agencies within the unified regulatory agenda<sup>9</sup> and also by requiring independent agencies to submit their proposals for inclusion within the annual regulatory plan, allowing the Vice President an opportunity to advise and consult.<sup>10</sup>

President George W. Bush decided to use President Clinton's executive order 12,866 for regulatory oversight. The Bush administration has focused on improving regulatory oversight in a number of ways: First, OMB now routinely puts information concerning its regulatory analysis and review process on its web site, making the regulatory process more transparent; second, OMB has introduced 'prompt letters', designed to encourage agencies to explore new areas in which regulation might deliver benefits that exceed costs;<sup>11</sup> third, by trying to improve the underlying science and economics that goes into decisions – OMB issues guidelines to agencies on both information quality and regulatory analysis.<sup>12</sup>

Congress has been slower to support efforts to require the balancing of benefits and costs of major regulations. In 1982 the Senate unanimously passed such a law, but it was defeated in the House of Representatives.<sup>13</sup> Two primary environmental statutes that allowed the balancing of benefits and costs prior to the mid-1990s are the Toxic Substances Control Act<sup>14</sup> and the Federal Insecticide, Fungicide, and Rodenticide Act.<sup>15</sup> Recently, Congress has shown greater interest in emphasizing the balancing of benefits and costs. Table 1 reviews regulatory reform initiatives, which could help improve regulation and legislation.

Table 1 suggests that Congress now shares the concern of the executive branch that the regulatory system is in need of repair and could benefit from more economic analysis.<sup>16</sup> All reforms highlighted in the table emphasize a

<sup>8</sup> Id.

<sup>9</sup> Id., at § (4)(b).

<sup>10</sup> Ibid. at § 4(c).

<sup>11</sup> See Robert Hahn and Cass Sunstein, 'Regulatory Oversight Takes Exciting New Tack', *AEI-Brookings Joint Center*, 2001. For examples of prompt letters, see OIRA website at [http://www.whitehouse.gov/omb/inforeg/prompt\\_letter.html](http://www.whitehouse.gov/omb/inforeg/prompt_letter.html).

<sup>12</sup> See OMB 2003 Report for guidelines for conducting regulatory analysis and OMB (2003b) for information quality guidelines.

<sup>13</sup> Ibid.

<sup>14</sup> See 15 USC. § 2605(a) (1994) (describing an allowed balancing of 'risk of injury to health or the environment').

<sup>15</sup> See 7 U.S.C. § 136a (1994) (allowing regulation to prevent unreasonable adverse effects on the environment).

<sup>16</sup> See, e.g., Robert Crandall *et al.*, *An Agenda for Federal Regulatory Reform* (AEI-Brookings Joint Center for Regulatory Studies, 1997), available at [http://aei-brookings.org/admin/pdffiles/agenda\\_for\\_reg\\_reform.pdf](http://aei-brookings.org/admin/pdffiles/agenda_for_reg_reform.pdf) (noting that 'recent legislative debates masked a broad consensus among knowledgeable observers on the need for regulatory reform').

Table 1. Regulatory Reform Initiatives

Unfunded Mandates Reform Act of 1995	CBO is required to estimate the costs of laws with new mandates in excess of \$50 million in any one year on state, local, and tribal governments, and in excess of \$100 million in any one year on the private sector. Likewise, an executive branch agency must prepare a cost-benefit analysis of regulations with new mandates in excess of \$100 million in any one year on state, local, and tribal governments or the private sector. The agency is required to choose the 'least costly, most cost-effective, or least burdensome alternative', unless the provisions are inconsistent with law or the head of an agency can explain why such an alternative was not adopted.
Small Business Regulatory Enforcement Fairness Act of 1996	An agency must submit each final regulation and the supporting analyses to Congress and the General Accounting Office. Congress has at least sixty calendar days to review major regulations before they can become effective. During that time, Congress can enact a joint resolution of disapproval that, if passed and then signed by the president, would void the regulation. In addition, strengthened judicial review provisions hold agencies more accountable for the impacts of regulations on small entities.
Regulatory Accountability Provision of 1996, 1997, and 1998	In separate appropriations legislation in 1996, 1997, and 1998, Congress required the Office of Management and Budget to submit an assessment of the annual benefits and costs of all existing federal regulatory programs to Congress for 1997, 1998, and 2000, respectively. The Office of Management and Budget already must review and approve analyses submitted by agencies estimating the costs and benefits of major proposed regulations. The annual report provisions build on this review process.
Pipeline Safety and Partnership Act of 1995	The Secretary of Transportation must issue a pipeline standard 'only upon a reasoned determination that the benefits of the intended standard justify its costs'.
Food Quality Protection Act of 1996	This Act eliminates the Delaney Clause for pesticides that set a zero-tolerance standard for carcinogens from residues in processed foods. In setting standards for raw or processed foods, the EPA will now establish a tolerance level to ensure 'a reasonable certainty of no harm' from pesticide residues. For pesticide products that exceed that negligible risk, the EPA may consider the benefits of the pesticide to justify granting a tolerance.
Safe Drinking Water Act Amendments of 1996	Under the original act, the maximum contaminant level (MCL) was to be set as close to the maximum contaminant level goal as 'feasible'. Feasible was defined as using the best technology available 'taking costs into consideration.' Under the new act, the EPA administrator 'shall publish a determination as to whether the benefits of the MCL justify, or do not justify, the costs'.
Truth in Regulating Act of 1999	Establishes a three-year pilot program under which individual agency Regulatory Impact Analyses are subject to independent evaluation by GAO, upon request by Congress.
Biennial Review Provision of the Telecommunications Act of 1996.	Requires Federal Communications Commission: (1) to review biennially its regulations pertaining to telecommunications service providers and broadcast ownership; and (2) to determine whether economic competition has made those regulations no longer necessary in the public interest.

Sources: Crandall *et al.* (1997); Hahn, (2000c).

trend towards considering the benefits and costs of regulation, although the effectiveness of the provisions remains unclear. Perhaps because of the politicized nature of the debate over regulatory reform, these reform efforts

have come about in a piecemeal fashion, and there is some overlap in the requirements for analysis.<sup>17</sup>

## II. THE GRAND EXPERIMENT IN REGULATORY REPORTING

In 1995, Congress passed a law aimed at having the government assess the economic impact of federal regulation.<sup>18</sup> The substantive requirement imposed by this law could have important implications for gaining insight into the workings of the federal regulatory process as well as the impact of federal regulation.<sup>19</sup> For the first time in history, a government agency was asked to produce a report tallying the overall costs and benefits of regulations issued by several different federal agencies. The US Office of Management and Budget (OMB), which has primary responsibility for regulatory oversight, was asked to produce the report. The report addresses several key issues, including the costs and benefits of federal regulation, the impact of federal regulation on local governments, and ways to improve federal regulation.

This legal innovation was important because regulation plays an increasingly important role in the US economy and the world economy.<sup>20</sup> Exactly how large a role regulation plays in the US and world economies is difficult to say, but many scholars believe it has a substantial impact.<sup>21</sup> For example, expenditures on federal health, safety and environmental regulation are estimated to be on the order of \$200 billion annually or about 2% of

<sup>17</sup> There has been some recent interest in Congress in reducing this overlap by establishing a single congressional agency that would have the responsibility for assessing the government regulation. This agency would be similar to the Congressional Budget Office, but it would have responsibility for regulation. In principle, such an agency could help stimulate better analysis and review of agency regulations by providing an additional source of information. See Robert W. Hahn and Robert E. Litan, 'Joint Testimony before the Committee on Governmental Affairs,' U.S. Senate, 'The Regulatory Right-to-Know Act and the Congressional Office of Regulatory Analysis Act,' (April 1999) at [http://www.aei-brookings.org/publications/testimony/testimony\\_99\\_01.pdf](http://www.aei-brookings.org/publications/testimony/testimony_99_01.pdf).

<sup>18</sup> This section draws on Robert Hahn and Mary Beth Muething, 'The Grand Experiment in Regulatory Reporting,' 55(3) *Admin. L. Rev.* (2003), at 608–42.

<sup>19</sup> Treasury, Postal Services and General Government Appropriations Act, 1997 (P.L. 104–208). See section 645 (a).

<sup>20</sup> However, a significant shortcoming of the Congressional mandate that requires OMB to report on the costs and benefits of federal regulation is that it does not apply to independent agencies. In its 2002 report, OMB notes that it 'does not review regulations of the independent agencies or any regulations that are not determined to be "significant" under the E.O. 12866 definition.' See also *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, Office of Management and Budget (2002) at 38, available at [http://www.whitehouse.gov/omb/inforeg/2002\\_report\\_to\\_congress.pdf](http://www.whitehouse.gov/omb/inforeg/2002_report_to_congress.pdf) [hereinafter OMB 2002 Report].

<sup>21</sup> See, e.g., Thomas D. Hopkins, *Profiles of Regulatory Costs*, U.S. Small Business Administration, Washington, Nov. 1995, available at <http://www.sba.gov/ADVO/research/>.

GDP.<sup>22</sup> In its 2002 report to Congress on the costs and benefits of federal regulation, OMB notes that the total costs of major regulations issued between April 1995 and September 2001 are estimated to be between \$50 and \$53 billion annually.<sup>23</sup> The same report estimates that the benefits range from \$48 to \$102 billion annually.<sup>24</sup> The report, however, does not provide aggregate best estimates to determine whether the likely sum of benefits of all regulations during this period exceeds the sum of the costs.<sup>25</sup>

Earlier OMB reports suggested that the benefits of regulation could be substantial. For example, in its 2000 cost-benefit report, OMB cites an Environmental Protection Agency (EPA) estimate of \$96 billion for the benefits of the Clean Air Act. Two years earlier, EPA had estimated the benefits of the Clean Air Act to be between \$56 billion and \$1.5 trillion.<sup>26</sup>

Critics of the OMB report felt that the report would be used simply to highlight the costs of regulation and understate the benefits because benefits are sometimes harder to quantify than costs. Proponents of the report saw it as a way of providing greater regulatory transparency and accountability.<sup>27</sup> In particular, supporters of policy analysis and greater regulatory accountability felt that there was a need to provide more systematic and timely information on the overall costs and benefits of federal regulation.<sup>28</sup>

Before the requirement for a government report on federal regulatory costs and benefits, little work had been done in this area. The work that was done

<sup>22</sup> The draft of OMB's 2002 report on the costs and benefits of regulation estimated the aggregate cost of federal health, safety, and environment (social) regulation to be between \$181 and \$277 billion (2001 dollars). See Table 11 of Draft Report to Congress on the Costs and Benefits of Federal Regulations, 67 *Federal Register* at 15037 (2002). [hereinafter OMB 2002 Draft Report]. 2001 GDP was estimated by BEA as \$10.2 trillion (2001 dollars). See Bureau of Economic Analysis, National Accounts Data: Current-dollar and 'real' GDP, available at <http://www.bea.gov/bea/dn1.htm> (last visited 23 July 2002). 2001 figures (in current dollars) for Medicare spending (\$214 billion) and corporate income tax receipts (\$192 billion) are from OMB, The Budget for FY 2003, Historical Tables, Table 8.5, at 132; Table 14.1, at 286, available at <http://www.whitehouse.gov/omb/budget/fy2003/pdf/hist.pdf>.

<sup>23</sup> See OMB 2002 Report *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, Office of Management and Budget, Table 8 (2002), at 39.

<sup>24</sup> See OMB 2002 Report, above n 23, at 39.

<sup>25</sup> This is a point we discuss later in §3, *Evaluation*, at 10.

<sup>26</sup> Costs of the Clean Air Act were estimated at \$20 billion in EPA's 1999 report and between \$84 and \$140 billion in 1997. See OMB 2000 Report to Congress, at 19–22. For a critique of the particulate matter benefits, see Randall Lutter and Richard B. Belzer, *EPA Pats Itself on the Back*, 23 *Regulation* 3 (2000), at 23.

<sup>27</sup> See Robert W. Hahn and Robert E. Litan, *Improving Regulatory Accountability*, Washington, DC: American Enterprise Institute and The Brookings Institution (1997), available at [www.aei.brookings.org/publications/books/improving\\_reg\\_accountability.pdf](http://www.aei.brookings.org/publications/books/improving_reg_accountability.pdf).

<sup>28</sup> See Kenneth Arrow *et al.*, *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation: A Statement of Principles* (1986), available at [http://aei.brookings.org/publications/books/benefit\\_cost\\_analysis.pdf](http://aei.brookings.org/publications/books/benefit_cost_analysis.pdf), for appropriate use of cost-benefit analysis in federal regulations. [hereinafter *Benefit-Cost Principles*].

tended to focus on the impact of the stock of existing regulation, as opposed to the flow of new regulations that are added each year. Early work by Weidenbaum and DeFina, and Litan and Nordhaus estimated the costs of federal regulation.<sup>29</sup> Subsequent work by Hahn and Hird estimated the costs and benefits of federal regulation.<sup>30</sup> More recently, Hopkins focused on estimating the costs of regulation over time, including costs associated with paperwork.<sup>31</sup> Winston provided some useful estimates of the economic impact of regulation and deregulation in the US<sup>32</sup> With one exception – work by the Center for the Study of American Business under the leadership of Murray Weidenbaum – none of this research provided annual updates. Moreover, the work by the Center for the Study of American Business was fairly narrow in scope, focusing on the administrative costs associated with federal regulatory agencies.<sup>33</sup>

In response to regular Congressional mandates, OMB has produced six reports on the costs and benefits of federal regulation. In this paper, we summarize these reports using objective measures.<sup>34</sup> In an appropriations bill, Congress requested each of the five annual reports issued by OMB since 1997.<sup>35</sup> Each year, Congress has asked for the same core components: estimates of the costs and benefits of federal regulation; an assessment of the impact of federal regulation on state and local government; and recommendations for ways to improve federal regulation.<sup>36</sup> The first two laws that directed

<sup>29</sup> See Murray L. Weidenbaum and Robert DeFina, *The Cost of Federal Regulation of Economic Activity*, Washington D.C.: American Enterprise Institute (1978). See also Robert E. Litan and William D. Nordhaus, *Reforming Federal Regulation* (New Haven, CT: Yale University Press, 1983).

<sup>30</sup> See Robert W. Hahn and John A. Hird, *The Costs and Benefits of Regulation: Review and Synthesis*, 8 Yale J. On Reg. 1 (Winter 1991).

<sup>31</sup> See, for example, Thomas D. Hopkins, 'Profiles of Regulatory Costs', Report to U.S. Small Business Administration (November 1995).

<sup>32</sup> See Robert W. Hahn, *Government Analysis of the Benefits and Costs of Regulation*, 12 J. Econ. Persp. 4 (1998), at 201–10. For a discussion of the impact of regulation and deregulation outside the US, see, e.g., Luis Guasch and Robert W. Hahn, 'The Costs and Benefits of Regulation: Implications for Developing Countries', 14 The World Bank Research Observer 1 (1999), at 137–58.

<sup>33</sup> Annual estimates of the impacts of federal regulation were provided by the Center for Study of American Business, but these focused on the administrative costs associated with regulation and the number of federal personnel in regulatory agencies. See, e.g., Center for Study of American Business, at <http://csab.wustl.edu/csabarchive.html>.

<sup>34</sup> There have been several evaluations of specific reports as well as the process, but no evaluation that takes a careful look at how the reports have evolved over time.

<sup>35</sup> Although it did not publish a final report in 1998, OMB has fulfilled Congress' reporting requirement for five of the past six years. OMB issued the first report at the end of 1997, the same year that the report was mandated. OMB issued the second report with Congress' direction in the *Treasury and General Government Appropriations Act of 1998* (§ 625, P.L. 105–61). The final report was not published, however, until January of 1999. Subsequent reports were also published one year after the Congressional acts that asked for them were passed.

<sup>36</sup> OMB is required by law to publish a draft copy of its yearly report on Costs and Benefits of Federal Regulation, and to solicit comments from the public on its draft report before publishing the final report. OMB is also required to go through a peer-review process before publishing its final report each year.



the OMB to produce the cost-benefit report specified that the report should suggest ways to 'reform or eliminate any Federal regulatory program or program element that is inefficient, ineffective, or is not a sound use of the Nation's resources'.<sup>37</sup> Subsequent Congressional mandates were more general and did not explicitly ask OMB to identify regulatory *programs* when making reform suggestions.<sup>38</sup>

In scoring the OMB reports, we evaluate OMB's assessment of the information in the regulatory impact analyses (RIAs)<sup>39</sup> that are performed for each major federal regulation by the agency that issues that regulation. Much of the information included in the OMB report comes from different federal agencies. Therefore, the amount and quality of the information on overall costs and benefits that OMB is able to report is directly related to the quality of the analyses submitted by the agencies.

We examined a number of issues related to costs, benefits, net benefits, and recommendations by OMB.

### A. Costs and benefits

In scoring the reports, we have noted whether the report met certain criteria related to the reporting of costs and benefits (see Table 2).

Executive Order 12,866 requires agencies to assess the costs and benefits of regulations that are economically significant and defines a 'significant regulatory action' as a rule 'that is likely to have an annual effect on the economy of \$100 million or more'. There are several points worth noting:

- First, a majority of Regulatory Impact Analyses for new regulations examined in the past five OMB reports quantifies some measure of costs and benefits.
- Second, in the past four reports, benefits are monetized less frequently than costs.
- Third, a small number of regulations quantify neither costs nor benefits. In 1997, 5 of 21 regulations fell into this category. In 2002, three regulations failed to quantify costs or benefits, compared to two regulations in 2001. Unfortunately, in 1998 and 1999, OMB's reports did not indicate the number of regulations failing to quantify costs and benefits.
- Fourth, the numbers that OMB does provide cannot be easily compared across the different yearly reports. OMB states that 'agencies monetized all the benefit estimates that they were able to quantify in *eight* cases' and that 'in *five* cases, agencies provided some of the benefit estimates in

<sup>37</sup> See *Treasury and General Government Appropriations Act of 1998*, (§ 625, P.L. 105–61).

<sup>38</sup> A regulatory program is broader than a specific regulation and may include several regulations that have related purposes or are mandated by the same law. An example of a regulatory program is the Superfund program.

<sup>39</sup> Regulatory impact analysis and regulatory impact assessment are used interchangeably.

Table 2. Information on Regulations and their Costs and Benefits

	1997	1998	2000	2001	2002	2003
Date range of economically significant final regulations that were not included in a previous report	(4/96–3/97)	(4/95–3/96); (4/97–3/98)	(4/98–3/99)	(4/99–3/00)	(4/99–9/01)	(10/92–3/95); (10/01–9/02)
Does OMB take the agency's numbers as given?	Yes	Yes	Yes	Yes	Yes	Yes
How many new non-transfer regulations were discussed in the report:	21	22	22	12	34	6
Did the report state how many new social regulations (or 'non-transfer') regulations:						
quantified some costs?	No	19 of 22	16 of 22	8 of 12	27 of 34	3 of 6
monetized some costs?	16 of 21	19 of 22	16 of 22	8 of 12	27 of 34	3 of 6
quantified some benefits?	14 of 21	16 of 22	16 of 22	9 of 12	20 of 34	5 of 6
monetized some benefits?	8 of 21	13 of 22	12 of 22	7 of 12	19 of 34	5 of 6
monetized at least some costs and some benefits in the agency's analysis?	No	13 of 22	10 of 22	6 of 12 <sup>i</sup>	12 of 34	3 of 6
quantified neither costs nor benefits?	5 of 21	No	No	2 of 12	3 of 34	1 of 6
Are any quantitative cost or benefit estimates provided for independent agencies' regulations?	Yes	Yes	Yes	Yes	Yes	Yes
Did OMB monetize any costs or benefits that the agencies' RIAs did not?	No	Yes	Yes	No	Yes	No
Did OMB monetize lives saved when an agency did not?	No	Yes	Yes	No	Yes	Yes
Did OMB monetize any pollution benefits?	No	Yes	Yes	Yes	Yes	Yes

Source: Adapted from Hahn and Muehling (2003).

monetized and quantified form, but did not monetize other, important components of benefits'. Finally, 'in *three* cases, agencies provided quantified but not monetized benefit estimates'.

- Fifth, the fraction of new regulations reporting monetized estimates for both some costs and some benefits is below 50% in three of the four years for which information is provided.

A valuable part of OMB's second, third, and fifth yearly reports is a set of tables in which OMB standardizes yearly costs and benefits by agency. OMB monetizes the agencies' quantified estimates when it is able to, and converts the estimates to a standardized dollar year so that comparisons can be made across agencies and years. The 2002 report states that in 'assembling estimates of benefits and costs... OIRA has monetized quantitative estimates where the agency has not done so'.

We do not feel the estimates reported by OMB in these tables are either standardized or comprehensive enough to be used in reliably assessing net benefits. While OMB does monetize some benefits that the agencies have only quantified, these tables take agency numbers as given when an agency has provided a monetized estimate, even though different agencies may use different assumptions to monetize costs and benefits. OMB notes that 'to the extent that agencies have adopted different monetized values for effects – for example, different values for a statistical life or different discounting methods – these differences remain embedded in the tables'. Finally, the tables omit any valuation of benefits that the agencies did not quantify. Any cross-year or cross-agency comparison that the tables do allow one to make is still incomplete.

All of the reports address the issue of information collection costs, such as those associated with additional paperwork. In the past three reports, OMB has also provided a table summarizing information collection costs that result from federal regulation. The table breaks down costs imposed by executive and independent agencies. These costs are significant in some cases, but they do not include many critical costs of regulation, such as impacts on a firm's production processes and effects on consumers unrelated to paperwork.

## B. Net benefits

For each year, less than half of the new non-transfer regulations would unambiguously pass a cost-benefit test based on quantified estimates of benefits and costs. At the same time, only a small fraction would unambiguously fail a cost-benefit test. By inference, most regulations either do not provide enough information to compare costs and benefits, or there is a large enough range of uncertainty in the agencies' estimates to put the regulations in a gray area, where they neither unambiguously pass nor fail. For example, in OMB's 2002 report we calculate that net benefits were not obviously positive or negative

for 23 of 34 new regulations. While it may be sensible to use ranges when estimating costs and benefits to reflect uncertainty, it is difficult to interpret ranges. First, the agencies rarely provide information about their degree of confidence that the actual value of benefits or costs falls within the range. Second, when estimated ranges of costs and benefits produce a net benefit estimate that ranges from negative to positive, it is unclear whether a regulation is likely to pass or fail a cost-benefit test.

The number of regulations passing or failing a cost-benefit test could indicate the effectiveness of the OMB oversight process, although there are clearly other important factors, since the flow of regulations is not random and is determined by forces outside of OMB's control – most notably Congress. The number of regulations unambiguously passing a cost-benefit test does not show any obvious pattern for new regulations over the past five reports.

The reports also consider the issue of aggregate net benefits. Aggregate net benefits can provide useful information on whether a particular set of regulations or programs are enhancing economic welfare at a particular point in time or over a time period. However, as several authors and OMB have pointed out, there can be problems with adding up the benefits and costs of regulation across different studies because of differences in assumptions and baselines. The 2002 report was the first *not* to include any information on aggregate net benefits of new regulations.

In the past two years, OMB has discontinued the practice of forecasting aggregate net benefits over time. OMB's 1998 and 2000 reports included tables that forecasted the costs and benefits of federal regulations in the years 2005, 2010, and 2015. In both its 1998 and 2000 reports, OMB forecasted and summed future costs for individual regulations in a summary table.

Sometimes, aggregate benefits can be disaggregated to provide more informative estimates. For example, it may not make sense to combine the net benefits of airline deregulation with the net benefits of safety regulation, but it might be reasonable to determine whether EPA's Superfund program's benefits are likely to exceed its costs. Generally, OMB has not provided much useful information on the benefits and costs of specific programs. In the 2002 report, however, it did begin to provide some data on benefits and costs by agency, information that could be useful for comparing net benefits of regulations across agencies.

### C. OMB's recommendations for reforms

One of the initial aims of Congress was to have OMB suggest ways to 'reform or eliminate any Federal regulatory program or program element that is inefficient, ineffective, or is not a sound use of the Nation's resources'. OMB has generally been slow to suggest specific reforms. So far, it has not identified any regulatory programs for elimination or improvement. In the 2001 report, however, OMB endorsed specific suggestions from the public about reforming, and in some cases eliminating, individual regulations. In 2002, OMB's

report included information on the status of efforts to improve the regulations that were identified as high priority reform opportunities in the 2001 report. OMB has taken further measures to improve federal regulation by encouraging agencies to examine the impact of new, economically significant regulations. The 2002 report states that 'in response to our request for regulatory reform proposals, we received suggestions on 316 unique regulations and guidance documents covering 26 Federal agencies', and that OMB has made the decision to change the way it evaluated reform suggestions from an OMB-initiated process to an agency-initiated process. In September of 2001, OMB introduced the 'prompt letter', which encourages agencies to issue specific regulations whose benefits exceed costs.

#### D. Overall picture

The picture that emerges from these reports is intriguing. OMB is focusing less on aggregate estimates of the impacts of regulatory activity and more on improving the process and particular regulations. OMB has *not* used its own in-house expertise to render judgments on the quality of regulatory analysis given to it by the agencies.

OMB is, however, taking greater advantage of suggestions from interested parties to identify regulations that are in need of reform or elimination. It is also actively searching to help identify new regulations whose net benefits are likely to be substantial, and using prompt letters to alert agencies to new regulatory opportunities. Finally, changes in OMB's use of the return letter suggest that OMB may be assessing and making changes to its oversight role. OMB's use of the return letter is authorized in Executive Order 12,866, which states that when OMB denies approval of a regulation that an agency has submitted, it must also send a letter explaining why the regulation was not approved. OMB may send a return letter to explain a problem it has with a draft rule or with a draft analysis of the rule's impact. OMB issued a higher number of return letters in the year preceding its most recent report than it had since 1984 and also instituted the practice of making return letters publicly available on its website.

OMB is also making attempts to improve the quality of regulatory analysis and to make the regulatory process more transparent. In its 2000 Report, OMB published guidance to agencies on how to conduct Regulatory Impact Analyses. OMB announced in its 2002 draft report that it was soliciting comments on what should be considered in updating the guidance that was published in the 2000 report. This year's final report lists 5 topics that OMB intends to consider in developing updated guidance to agencies.

Since the most recent report to Congress, OMB has involved all of the executive agencies in significant actions to improve the quality of information disseminated by Federal agencies. A 2001 Appropriations Bill directed OMB to issue government-wide guidelines that would improve the quality, objectivity, utility and integrity of Federal agencies' information. OMB issued final

information quality guidelines to all agencies in September 2001. In these guidelines, OMB directed all agencies to issue their own agency-specific guidelines that described how the agency would: comply with OMB's information quality standards; ensure the correction of information that did not comply with the guidelines; and report to the OMB director on complaints received about information quality. In an October 4, 2002 memo, the OIRA administrator reported that OMB had completed a review of the different agency-specific guidelines, and that '[OMB's] implementation of the Information Quality Law represents the first time that the Executive Branch has developed a government-wide set of information quality guidelines, including agency-specific guidelines tailored to each agency's unique programs and information'.

OMB has recognized that the Internet is a valuable way of making regulation transparent. OMB has made more information available to the public by publishing prompt letters, return letters, memos, and press releases on its own website. There is some indication that OMB's efforts to facilitate public involvement in the regulatory process are working: OMB received 1,700 comments on 267 regulations and 49 guidance documents in response to its most recent request for reform suggestions. OMB has also directed agencies to use the Internet to make more information available to the public: 'Agencies should use their websites to keep the public informed about information on a timely basis. Specifically, each agency or office should establish an information quality site on its website'.<sup>40</sup> In addition, OMB's willingness to work with agencies to make Regulatory Impact Analyses more available on the Internet is highly commendable. This online collaboration will make the regulatory process more transparent and hold lawmakers more accountable.

### III. EUROPEAN EXPERIENCE

Regulatory impact assessment is necessary to help the EU improve its overall level of economic, social, and environmental well-being.<sup>41</sup> Regulatory impact

<sup>40</sup> See *Memorandum for the President's Management Council, Information Quality Guidelines – Principles and Model Language*, Office of Management and Budget (2002).

<sup>41</sup> For guidelines on impact assessment in the European Union and the importance of considering economic, social, and environmental impacts, see the EU's *Communication in Impact Assessment* (COM(2002)276 final). See, e.g., Frank Vibert, *The EU's New System of Regulatory Impact Assessment – A Scorecard*, European Policy Forum (2004) provides some reasons for impact assessment. See also Bruce Ballantine, *Regulatory Impact Analysis: Improving the Quality EU Regulatory Activity* (The European Policy Centre, September, 2001), [hereinafter *Improving the Quality*], statement by Stanley Crossick, Chairman of the European Policy Centre: 'The Council of Ministers has declared that the European Union should be the most competitive, knowledge-based economy by 2010. It has, in addition, ambitious public health, social, and environmental objectives. This requires a regulatory framework that, at one and the same time, supports the long-term competitiveness of European business, while facilitating the development of the European social model. Regulatory impact analysis can help legislators to achieve these, often-conflicting objectives . . .'. See also Scott Jacobs, 'Regulatory Reform: Time for Action', *The OECD Observer* 206 (Jun./Jul. 1997) (arguing for regulatory reform in OECD countries).

assessment can take many forms, including benefit-cost analysis and cost-effectiveness analysis.<sup>42</sup> In order to measure the impact of a regulation, the impact assessment should contain some basic features, such as quantified benefits, quantified costs, and alternatives to the regulation. Adequate oversight institutions should establish criteria for a high-quality impact assessment, ensure that impact assessments meet those criteria, return regulations when the benefits do not outweigh the costs, and promote regulations that are likely to have benefits that exceed costs. Although the quality of assessment and oversight is higher in some European member states than others, the overall quality throughout Europe is generally poor.<sup>43</sup> In this section, we describe the state of impact assessment and oversight in Europe and identify specific areas for improvement.

### A. Structure of oversight

The member states and the EU have adopted different oversight mechanisms for quality control and monitoring of the regulatory impact assessment process. One possible reason is that the different member states and their respective Directorates Generals do not share a single regulatory culture with each other or with the European Commission.<sup>44</sup> Some states, such as the UK, Denmark, and Belgium, have centralized oversight. A central unit directs the actions of agencies or line ministries, works to prevent the implementation of inefficient regulations, and provides guidance to agencies on regulatory

<sup>42</sup> OMB states, 'The size of net benefits, the absolute difference between total benefits and total costs, is the key to determining whether one policy is more efficient than another.' See OMB 2003 Report, at 5516. Benefit-cost analysis says something directly about the economic efficiency of a policy. Cost-effectiveness analysis typically takes the goal of a policy as *given*, and provides information that will help achieve that goal at the lowest social cost.

<sup>43</sup> However, it is important to keep in mind that the uses of regulatory impact assessment (RIA) in Europe differ from those in the US. For discussion of how RIAs are used in the US and Europe, see Claudio Radaelli, 'Getting to Grips with the Notion of Quality in the Diffusion of Regulatory Impact Assessment in Europe', *Paper prepared for conference on Regulatory Impact Assessment: Strengthening Regulation Policy and Practice*. (November, 2003), at 12–13. [hereinafter *Getting to Grips*]: (In the US, 'the dominant criterion is efficiency and the main logic is technical. Negotiation and standard operating procedures are not absent, but they are not overwhelming . . . In most EU countries, RIA is a communication tool between government and citizens. The "regulator" performing RIA is not an independent agency, but a Minister reporting to the cabinet. Surprisingly enough, most independent regulators in Europe have not even been requested to perform impact assessment. . . . Not only does the logic of negotiation dominate the behaviour of Ministers engaged in impact assessment, it also characterizes the interactions between public administration and pressure groups, and between civil servants and politicians. . . . This is why in some countries RIA does not produce a final set of figures showing if the benefits justify the costs of proposed regulation, but rather a set of partial estimates that are then used by policy-makers in a "mode" that is more "negotiation" than "technical analysis of options". Add to this that in all EU continental countries and the UK RIA has become a communication tool.'))

<sup>44</sup> However, the directorates-generals of the various member states can help facilitate a harmonized regulatory culture. This harmonization can begin in areas where the European Commission has direct regulatory powers, such as competition, telecommunications, and energy.

impact assessment.<sup>45</sup> Others, such as Germany, Norway, Sweden, and the Netherlands have fragmented oversight in which a coordinating unit fosters communication among relatively autonomous agencies and is typically concerned with the effects of regulation on business.<sup>46</sup> These oversight institutions, particularly the central units, are well situated to evaluate the quality of impact assessment. Therefore, the type of oversight mechanism can influence the technical quality of the RIA. Many European countries that lack a central unit responsible for quality control and monitoring perform inadequate regulatory impact assessments or none at all.<sup>47</sup> Table 3 characterizes regulatory oversight and assessment for six EU countries, the United States, Canada, New Zealand, and Australia.

Table 3 shows whether a country has a central or coordinating oversight unit, performs regulatory impact assessments, and conducts benefit-cost analyses. None of the six EU countries in the table have central oversight

Table 3. Oversight in OECD Countries

Country	Central unit	Coordinating unit	Regulatory impact assessments?	Benefit-cost analysis requirements?
Australia	Yes	Yes	Yes	Yes
Austria	No	Yes	No	No
Canada	Yes	No	Yes	Yes
Germany	No	Yes	No	No
Netherlands	No	Yes	No	No
New Zealand	No	Yes	Yes	No
Norway	No	Yes	Yes	No
Sweden	No	Yes	No	No
UK	Yes	No	Yes	Yes
USA	Yes	No	Yes	Yes

Sources: International Study: Efforts to Reduce Administrative Burdens and Improve Business Regulation: Final Report (August 2003), OECD (1997).

Notes: The four countries that do not have regulatory impact assessments perform some form of analysis. Austria, Germany, and Sweden have impact check-lists, which qualify as impact assessments under the OECD's definition. Netherlands has an expert assessment, which would also qualify as an impact assessment under the OECD's definition. Central Units are: Office of Regulatory Review in Australia; Regulatory Affairs and Orders in Council Secretariat (RAOIC) in Canada; Cabinet Office, Regulatory Impact Unit (RIU) in UK; and The Office of Management and Budget (OMB) in the United States. Examples of Independent Units are the Small Business Administration in the United States and the Better Regulation Task Force in the UK.

<sup>45</sup> A central unit is typically located in the office of the head of government. See *International Study: Efforts to Reduce Administrative Burdens and Improve Business Regulation*, Danish Commerce and Companies Agency (2003), at 71. [hereinafter *International Study*]

<sup>46</sup> See *International Study* (2003) for definitions of the central and coordinating units. ("The location of the coordinating unit is typically in the Ministry of Business Affairs/Economic Affairs, and it is more narrowly concerned with the effects of regulation on business.")

<sup>47</sup> Radaelli warns, however, that if other departments or agencies perceive central units as 'intrusive', efforts to institutionalize RIAs will fail. See Radaelli, *Getting to Grips* (2003). The Netherlands provides an example an EU country where a unit independent of the central government assesses regulatory burdens on business. This unit, however, does not conduct quantitative RIAs. For more information on this independent unit, see [www.actal.nl](http://www.actal.nl).



units. Interestingly, all of the countries with central units do benefit-cost analyses, while those without central units do not perform benefit-cost analyses.<sup>48</sup>

Oversight has also been fragmented at the EU level.<sup>49</sup> One reason is that the different Directorates-Generals in the European Union do not share a single regulatory culture.<sup>50</sup> Another is that the EU has lacked a central focal point for impact assessment, but this has begun to change as overall coordination of the RIA process improved dramatically since 2002.<sup>51</sup>

Benefits are quantified less frequently in the EU and its member states than in the US at the federal level for at least three reasons. First, unlike the US regulatory oversight agency, the unit that oversees the regulatory process is usually a coordination unit that lacks the authority to review regulations and analyses.<sup>52</sup> The Ministry of Economic Affairs in the Netherlands, for instance, coordinates with other agencies to produce impact assessments.<sup>53</sup> Second, impact assessments in the EU are frequently used as forms of negotiation, which are subject to interest group capture, rather than as tools for direct decision-making.<sup>54</sup> Third, benefits may often be assumed to exist and not questioned at all.

<sup>48</sup> We are not suggesting that the centralized unit is the reason that these countries do benefit-cost analysis.

<sup>49</sup> See Claudio Radaelli, 'The Diffusion of Regulatory Impact Analysis: Best Practice or Lesson Drawing', 43 *Euro. J. of Polit. Res.* (2004), at 725–49. [hereinafter *Diffusion of Regulatory Impact Analysis*] See also Ballantine, *Improving the Quality* (2001).

<sup>50</sup> Belgium, for example, defines better regulation in terms of reducing administrative burdens of firms, and therefore situates the 'central unit' in the Ministry of Business. See Ballantine, *Improving the Quality*, above n 49 (2001). The UK, on the other hand, defines better regulations as those needed to protect people at work, consumers and the environment while also striking the right balance so that they do not impose unnecessary burdens on businesses or stifle growth. See United Kingdom Regulatory Impact Unit, available at <http://www.cabinetoffice.gov.uk/regulation/role/index.asp>.

<sup>51</sup> See Ballantine, *Improving the Quality*, above n 49 (2001). See also Radaelli, *Diffusion of Regulatory Impact Analysis* (2004): 'There have been several attempts to introduce partial forms of impact assessment in EU policy process, but only in 2002 did the Commission make the commitment to introduce a single, integrated form of RIA.'

<sup>52</sup> The coordination unit often does not have the power to make substantial changes to the analysis. See Danish International Study, at 49 ('The relationship between the unit and departments are to some extent voluntary or traded, and in the case of conflicting interests, the line ministries are free to choose the solution they prefer. The unit is equal in ranking to other line agencies, and must use 'soft tools' as support, communication, and education to promote its principles.') See for example Germany's impact assessments, *International Study* (2003): ('In general the business impact assessment is conducted with the help from interest groups that are most affected by the upcoming law. When the proposal is accepted as law, the initiating ministry has... to see whether side effects have occurred and if the costs are in proportion to the results.')

<sup>53</sup> In addition, it has an independent unit, known as ACTAL, which performs independent analyses and monitors the quality of RIAs. See ACTAL website, available at <http://www.actal.nl>. ACTAL focuses on measures of cost-effectiveness and alternatives that can achieve the same goal as a regulation, but at a lower cost.

<sup>54</sup> The notion that RIAs serve as the primary basis for regulatory decisions in the US is generally not true. They do inform decision-making, but as in Europe, laws and regulations are frequently designed in response to interest group pressures. See, for example, Robert Hahn, *Politics and Religion of Clean Air*, 13 *Regulation* 1 (Winter 1990). For a discussion of how the regulatory process works in Europe, see Radaelli, *Getting to Grips* (2003).

There are substantial differences in the requirements for regulatory analysis across member states. While many states do not have centralized oversight, they do have some requirements for regulatory analysis.<sup>55</sup> Table 4 provides an overview of regulatory reform efforts in nine EU member states and six non-EU member states.<sup>56</sup>

Except for the UK, none of the EU member states in Table 4 required benefit-cost analysis. However, some EU member states, such as Finland,

Table 4. Overview of Regulatory Reform Efforts Around the World

Country	Oversight of regulatory reform	Review of existing activities	Initiated	Analysis requirements
Australia	Permanent	Continuous	1985	Benefit-cost analysis
Austria	None	None	1992	Fiscal analysis recommended
Canada	Permanent	One-time	1977; revised 1986; 1992	Benefit-cost analysis or cost-effectiveness analysis; more complex analysis required for regulations with present value over CAN\$50 million.
Finland	Ad hoc	One-time	1970s; revised 1990	General impact analysis
Germany	Ad hoc	One-time	1984; revised 1989	Not mandatory; benefit-cost analysis suggested
Iceland	None	None	Proposed 1985	General impact/fiscal analysis proposed
Japan	Ad hoc	One-time	1987; revised 1988	General impact analysis as considered necessary by regulators
Netherlands	Permanent	Continuous	1985	General impact analysis
New Zealand	Permanent	One-time	1996	Fiscal analysis
Norway	Ad hoc	One-time	1985; revised 1995	Consequence (fiscal) analysis; benefit-cost analysis recommended as appropriate
Portugal	Ad hoc	One-time	n.a.	Fiscal analysis
Sweden	Permanent	One-time	1987; revised 1994	Consequence/distributional/fiscal analysis; includes benefit-cost analysis and cost-effectiveness analysis for regulations with significant negative effects.
United Kingdom	Permanent	One-time	1985; revised 1995	Benefit-cost analysis
United States	Permanent	One-time	1974; revised 1977, 1981, 1993, 1995	Benefit-cost analysis; more complex analysis required for 'economically significant' regulations

Source: OECD (1997a).

Notes: Permanent indicates an agency or unit is involved in regulatory administration. Ad hoc indicates that a temporary commission or task force exists. Continuous indicates that reviews are institutionalized on an ongoing basis. One-time indicates singular or occasional review(s).

<sup>55</sup> France and Italy, for example, have laws requiring regulatory impact analysis. These laws, however, do not seem to be strictly enforced. Most of the other EU countries do not have laws requiring regulatory impact analysis.

<sup>56</sup> See Robert W. Hahn, *Reviving Regulatory Reform: A Global Perspective* (2000), at 23, tbl. 2-2.

Germany, the Netherlands, Norway, Portugal, and Sweden institutionalized regulatory reviews.

The UK has been particularly active. The UK has created a centralized Regulatory Impact Unit that monitors the quality of benefit-cost analyses.<sup>57</sup> The RIAs produced by the UK are relatively extensive and quantify costs and benefits more than most, if not all, of the other EU member states. The audit evaluation performed by the Regulatory Impact Unit primarily entails scoring RIAs along several dimensions.<sup>58</sup> The UK also has an independent group, called the Better Regulation Task Force, which monitors the quality of RIAs.

The quality of impact assessment can depend on reporting mechanisms that increase accountability. One recent study attempts to compare attempts to assure quality across member states. Table 5, adapted from Radaelli (2004), provides four measures related to quality control for nine member states and the EU.

Table 5. Quality Control of the Regulatory Impact Analysis

	Central oversight	Annual report on RIA	RIA results made public when laws published	Public debate on the quality of the RIA process
Mexico	Y	N	NA	N
Canada	Y	Y	Y	Y
U.S.	Y	Y	Y	Y
Austria	Y	Y	Y	NA
UK	Y	N	Y	Y
Denmark	N	Y	Y	N
France	Y	N	N	N
Germany	N	N	Y	N
Netherlands	N	N	N	N
EU	N	N	N	Y

Source: Radaelli (2004).

Notes: Y = Yes, N = No, NA = Not Available.

<sup>57</sup> The National Audit Office within the Regulatory Impact Unit evaluates and scores many of the regulatory impact assessments. See, e.g., Ed Humpherson, *Evaluation of Regulatory Impact Assessments Compendium Report 2003–04*, National Audit Office (Mar. 2004). The National Audit Office scores RIAs along several criteria, such as whether an RIA estimated costs or benefits, whether the RIA process started early enough, and whether consultation was effective. See Danish International Study for a discussion of RIA implementation in various EU member states. In the UK, regulatory impact assessments have been mandatory since 1998 when introducing most new laws. The objective of RIAs in the UK is to obtain a quality improvement in new laws and to encourage public debate on the new legislation. The RIA has to be prepared as early in the regulatory process as possible. See Danish International Study, at 198–99 for a more extensive discussion of RIA implementation in the UK.

<sup>58</sup> The National Audit Office maintains that auditing and evaluation of RIAs are necessary. Even if an audit evaluation is required, however, there is no guarantee that RIAs will be of high quality, but such audits can be helpful in pointing out obvious deficiencies in RIAs. See, e.g., Robert Hahn *et al.*, *Assessing Regulatory Impact with Executive Order 12,866*, 23 Harv. J. L. & Pub. Pol'y 3 (2000).

The measures are central oversight for quality control and monitoring, annual reports on RIAs, public availability of RIA results, and public debate on the quality of RIA process. Table 5 shows that compared with the United States and Canada, which satisfy all four criteria, the EU member states perform poorly.<sup>59</sup> For example, France, Germany, and the EU itself satisfy only one criterion, and the Netherlands does not meet any.<sup>60</sup> In contrast, the United States and Canada pass on all four criteria. The European Commission does not publish an annual report that consolidates the costs and benefits of regulation or evaluates regulatory impact assessments.<sup>61</sup> Of the EU member states, Denmark produces annual reports on the costs of regulation to business, with no treatment of benefits; France, Germany, and the Netherlands do not have annual reports.

Since the 1980s, there have been many initiatives to improve regulatory quality at the EU level. A declaration annexed to the Maastricht Treaty required the European Commission to account for costs and benefits in its legislative proposals.<sup>62</sup> Since 1997 the EU, and its member states, have taken measures to implement regulatory impact analyses and issue guidelines for conducting them.<sup>63</sup> The Regulatory Policy Guidelines of 1996, issued by the President of the European Commission, seek to ensure that all legislation proposed by the Commission is subject to assessment.<sup>64</sup> In 2002, the European Commission began to oversee the development of regulatory analyses.<sup>65</sup>

In March 2000, the European Council included a 'Better Regulation' resolution in its Lisbon Conclusions, which stated that better regulation will play an important role in achieving the EU's goal of becoming the 'most competitive and dynamic knowledge-based economy in the world'.<sup>66</sup> And at the end of 2000, the Member States set up a high-level body, the Mandelkern Group, to

<sup>59</sup> The UK and Austria, which pass on three of the four measures, are exceptions.

<sup>60</sup> Although the Netherlands performs poorly on regulatory accountability, the Netherlands is making progress on regulatory impact assessment. For example, an independent task force, known as ACTAL, routinely performs cost-effectiveness analyses and examines alternatives to regulation. See above n 51.

<sup>61</sup> In 1997, the Commission published a report on business impact assessment, but the report was not evaluative. See Radaelli, *Getting to Grips* (2003).

<sup>62</sup> See Declaration 18 of the Maastricht Treaty.

<sup>63</sup> 'Regulatory impact analysis' can involve Cost-Benefit Analysis, Cost Effectiveness Analysis, and a range of other analytical tools. See *Regulatory Impact Analysis: Best Practice in OECD Nations*, Organization for Economic Cooperation and Economic Development (1997).

<sup>64</sup> See EU Regulatory Policy Guidelines (1996).

<sup>65</sup> See EC's guidelines on impact assessment and handbook for how to do an impact assessment. See 'Impact Assessment in the Commission: Guidelines' (European Commission 2002) and *Handbook for Impact Assessment in the Commission: How to Do an Impact Assessment* (2002). See Commission of the European Communities for the European Commission's commitment to introduce a single, integrated form of RIA.

<sup>66</sup> See Lisbon European Council (2000).

identify ways in which regulatory quality of new and existing EU legislation might be improved.<sup>67</sup> The mid-term review of the Lisbon Agenda in 2005 is likely to raise this issue again.

The EU has begun to conduct more regulatory impact assessments. In 2003, the European Commission selected 43 proposals for extended RIA treatment. For 2004, 46 are planned. Approximately 50% (20 total) of extended RIAs were completed by 2003, the first year.

Several scholars and practitioners have analyzed the quality of regulatory oversight in Europe. Table 6 provides a scorecard measuring the quality of the European Commission's early RIAs.<sup>68</sup>

Table 6 indicates that benefits were quantified and monetized in only half the cases, that costs were monetized and quantified more frequently than benefits, that all of the RIAs had positive net benefits, that none were rejected, and that half were redesigned. The fact that half were redesigned suggests, but does not prove, that RIAs may have had an impact. The fact that all passed a benefit-cost test suggests that the analyses may have been flawed, or that there is a very good pre-screening process. Interestingly, a large number of federal regulations also appear to pass a benefit-cost test in the US recently. One possible explanation, at least in the US, is that many regulations may pass a benefit-cost test;

Table 6. Scorecard: Quantification of First 20 EU RIAs (2003)

	Yes	No
Costs		
Quantified	14	6
Monetized	13	7
Benefits		
Quantified	10	10
Monetized	9	11
Estimation Method		
Best Estimate	12	8
Ranges	10	10
Upper/Lower Bands	3	17
Salient Sub Populations	10	10
Risk/Risk	7	9
Positive Net Benefits	17	0
Redesigns	10	10
Rejections	0	20

Source: Vibert (2004).

<sup>67</sup> For a more detailed description of the evolution of oversight in Europe, see Ballantine, *Improving the Quality* (2001). The Mandelkern Group Report established seven core principles to guide regulation: policy implementation options, impact assessment, consultation, simplification, access to regulation, structures, and implementation of European regulation of high quality. See Mandelkern Group on Better Regulation Final Report (November 2001).

<sup>68</sup> This table is adapted from Frank Vibert, 'The EU's New System of Regulatory Impact Assessment – A Scorecard', (*European Policy Forum*, 2004).

however, there may be parts of regulations that do not that are packaged with parts that do. Furthermore, even if a regulation passes a benefit-cost test, there may still be room for substantially improving the regulation.<sup>69</sup>

The picture that emerges from this brief overview is that centralized regulatory oversight in the EU is in its infancy.<sup>70</sup> The institutional mechanisms are not yet in place to assure a high level of quality. There is some recognition that there is a need to move in the direction of improving RIAs. We conclude that Europe has made some progress in improving regulatory analysis and oversight, but can do much more.

Because we are interested in offering recommendations for both the US and the EU, it is instructive to try to characterize the regulatory oversight problem at a general level. One problem arises in implementing sensible regulations at the state level. A state needs to decide whether to have a regulatory oversight authority, and if so, what its mission and structure should be. In general, such oversight authorities in the US have met with mixed success.<sup>71</sup> The record at the member state level is mixed as well. In general, there appears to be less emphasis on attempts to quantify benefits and costs than there are in the US at the federal level.

A second problem arises in implementing sensible federal regulations. The federal government needs to decide whether it wants a regulatory oversight authority and what its mission should be. As noted earlier, in response to growing concerns about the economic impact of regulation, the US government decided to develop a regulatory oversight capability within the Office of Management and Budget.

Europeans are now confronted with a similar set of issues, but face a different political environment. As explained to us, the institutions in the EU at the member state level are only now beginning to emerge. There is great concern about sovereignty issues, and there is great concern about designing institutions that are somewhat insulated from interest group pressures. At the same time, there appear to be concerns about a growing number of regulations that could emerge from Brussels that the states will be asked to implement.

In an ideal world, it probably makes sense to have a centralized oversight unit to assess new regulations and regulatory proposals at the member state level.<sup>72</sup> Arguments can be made based on scale economies. The regulations

<sup>69</sup> See Robert Hahn and Rohit Malik, *Is Regulation Good For You?*, 27 Harv. J. L. Pub. Pol'y 3 (2004), available at <http://aei-brookings.org/publications/abstract.php?pid=757>, for a more detailed discussion of this issue.

<sup>70</sup> A few EU member states, such as the UK, have made significant progress in doing regulatory impact assessments. The UK is a leader in RIA within the EU.

<sup>71</sup> See, e.g., Robert Hahn, *State and Federal Regulatory Reform: A Comparative Perspective*, 29 J. Leg. Stud. 2 (2000) (describing regulatory oversight at the state level).

<sup>72</sup> See Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation*, (Cambridge: Harvard University Press, 1993) (explaining why a centralized oversight agency or group is important to insulate regulatory decisions from interest group pressures).

frequently have more far-reaching impacts than state regulations, and there may be gains to having that expertise in one place that could share information with individual states.

Such an oversight agency should, in our opinion, be committed to promoting economic efficiency,<sup>73</sup> and it should be insulated from political pressures.<sup>74</sup> Again, in an ideal world, such an agency would build on the established expertise of existing agencies that do competent regulatory analyses. We recognize that both the US and the EU fall short of this ideal, but for different reasons.

#### IV. RECOMMENDATIONS FOR REFORM

We offer six recommendations for improving the quality and transparency of regulatory oversight and analysis: three recommendations for the United States and three for Europe. Our recommendations for the United States involve improving specific aspects of regulatory oversight, while our recommendations for Europe involve establishing institutions for oversight.

##### A. Recommendations for the United States

*Recommendation 1: OMB should apply its in-house expertise to evaluate and standardize the costs and benefits of regulations*

The major advantage that OMB analysts have over academics is that they are more familiar with the details of particular regulations and regulatory analyses. Therefore, OMB should evaluate agency estimates of the costs and benefits of regulations<sup>75</sup> and include an assessment of viable alternatives to those regulations. OMB should indicate agency assumptions it does not

<sup>73</sup> In addition to conducting standard economic efficiency assessments, an oversight agency in the European Union should also perform environmental and social assessments. See Commission of the European Communities, *Communication from the Commission on Impact Assessment* (2002) (COM(2002)276 final) for guidelines on impact assessment. The Communication states that the Assessment must provide economic, social, and environmental impacts. Economic impacts include effects on economic growth and competitiveness. Social impacts include effects on health, safety, and education, as well as distributional implications. Finally, environmental impacts include climate change and air, water and soil pollution. See also Jane Holder, *Environmental Assessment: The Regulation of Decision Making*, (Oxford University Press, 2005).

<sup>74</sup> It is important to recognize, however, that impact assessment is a tool to improve political decision making and not a substitute for it. Indeed, regulatory impact assessments can help curb some of the interest group pressures that result in irrational decisions. See Robert Hahn, *In Defense of the Economic Analysis of Regulation: A Response to the Critics*, (Washington, DC: AEI-Brookings Joint Center for Regulatory Studies, 2005).

<sup>75</sup> See *Informing Regulatory Decisions: Draft Report to Congress on the Costs and Benefits of Regulations*, Office of Management and Budget, Circular A-4, available at [http://www.whitehouse.gov/omb/inforeg/draft\\_2004\\_cbreport.pdf](http://www.whitehouse.gov/omb/inforeg/draft_2004_cbreport.pdf). (2004). [hereinafter OMB 2004 Draft Report] Office of Management and Budget OMB (2004, 6) ('While we have relied in many instances on agency practices in monetizing costs and benefits, our citation of, or reliance on, agency data in this report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefits and cost estimates.')

endorse for particular impact analyses and state its preferred assumptions. For example, OMB may not agree with the range of benefits and costs that the agency used in a rule analysis, or perhaps the agency did not describe health–health tradeoffs where it could have.<sup>76</sup> OMB should also standardize agency estimates of costs and benefits.<sup>77</sup> Assumptions for the value of a statistical life, the discount rate, base year and pollution values often differ by agency and rule. OMB should attempt to standardize values in order to facilitate comparison across regulations and agencies.<sup>78</sup> Otherwise, we cannot meaningfully compare or aggregate across regulations.

*Recommendation 2: Congress should pass a law requiring that all federal regulatory agencies comply with its guidelines and submit annual cost and benefit estimates of major regulations and selected antitrust activities to OMB*<sup>79</sup>

There are three sets of guidelines issued by OMB for the agencies doing the analyses of the regulations.<sup>80</sup> Unless the President decides that a regulation addresses an emergency, Congress should require that the proposed regulations not move forward if the agencies' Regulatory Impact Analyses fail to meet the guidelines. OMB's guidelines provide a set of principles for improving regulatory analysis and making the regulatory process more transparent. They should be required for all economically significant regulations from both executive and independent agencies.

Congress should also require that independent agencies estimate benefits and costs in the same format that executive agencies estimate them and

<sup>76</sup> For an excellent discussion of health–health tradeoffs, see Cass Sunstein, *Risk and Reason*, (Cambridge University Press, 2003) 133 ('The problem arises when the diminution of one health risk simultaneously increases another health risk.')

<sup>77</sup> OMB does not currently standardize agency estimates of costs and benefits. See OMB 2004 Draft Report, at 6 ('Any comparison or aggregation across regulations should also consider a number of factors that our presentation does not address. To the extent that agencies have adopted different methodologies – for example, different monetized values for effects, different baselines in terms of the regulations and controls already in place, different treatments of uncertainty – these differences remain embedded in Tables 1–3.')

<sup>78</sup> In some instances, different values may be justified. But standardizing can still be valuable. Agencies should also do sensitivity analyses, varying the discount rate, VSL, and pollution values. For an argument suggesting that the value of statistical life should vary across individuals, see, e.g., Cass Sunstein, 'Are Poor People Worth Less than Rich People? Disaggregating the Value of Statistical Lives', AEI-Brookings Joint Center, available at <http://www.aei-brookings.com/publications/abstract.php?pid=430>.

<sup>79</sup> The FTC and DOJ may need more data and observations to conclude whether antitrust enforcement has been positive or negative in the aggregate. For now, we can analyze whether enforcement of particular cases was positive or negative.

<sup>80</sup> The guidelines are: OMB Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements, which will be finalized this fall and will replace the Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, which were republished on 22 February 2002; and M-00-02, Guidance for Implementing E.O. 13132, 'Federalism', which was published on 28 October 1999. See OMB (2003a), OMB (2002), OMB (1999).



provide them to OMB.<sup>81</sup> Independent agencies, such as the Securities and Exchange Commission (SEC) and the Federal Communications Commission (FCC) recently issued significant regulations that could have benefited from benefit-cost analyses.<sup>82</sup>

Finally, Congress should require that the Federal Trade Commission (FTC) and the Department of Justice (DOJ) provide OMB with annual cost and benefit estimates of selected antitrust activities where available.<sup>83</sup> OMB should then summarize this data in its regulatory report. By requiring agencies to submit annual cost and benefit estimates to OMB, Congress can help improve agency discipline in documenting information from antitrust investigations. Congress should give the agencies some leeway in the actions they analyze – particularly because of the difficulties in doing such analysis.<sup>84</sup> Nonetheless, it should suggest that the FTC and DOJ focus on evaluating the impact of major antitrust decisions, including decisions not to block particular mergers.<sup>85</sup>

*Recommendation 3: OMB should issue a scorecard assessing the quality of regulations and regulatory analyses in the aggregate and ask the agencies to complete a scorecard for each major regulation*

Table 7 provides an example of a regulatory scorecard that addresses a regulation's overall impacts, costs and benefits, and alternatives.<sup>86</sup> Each agency should complete this type of scorecard for each regulation and submit it to OMB.

We encourage OMB to issue scorecards for two reasons. First, a standardized evaluation will help the public to compare regulatory analyses. Second, a scorecard should give agencies an incentive to conduct higher quality regulatory analyses. OMB must hold the agencies more accountable for the quality of their regulatory analyses.

<sup>81</sup> Under Executive Order 12866, OMB can require independent agencies to summarize alternatives and preliminary estimates of anticipated costs and benefits for economically significant regulations. See Clinton (1993) for Executive Order 12866, § 4(c), which outlines 'The Regulatory Plan': 'For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) . . . The Plan shall be approved personally by the agency head and shall contain at a minimum: A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits.'

<sup>82</sup> The recent Securities and Exchange Commission decision requiring Proxy Voting Policies and Proxy Voting Records by Registered Management Investment Companies could have benefited from a regulatory impact analysis. See, e.g., Randall Kroszner, *Comment on U.S. Securities and Exchange Commission Proposed Rule on Security Holder Director Nominations*, Washington DC: AEI-Brookings Joint Center (2003) for an analysis of a proposed SEC rule governing the inclusion of nominees of significant shareholders in company proxy voting materials.

<sup>83</sup> We recognize the challenges in doing retrospective economic analyses for non-merger activities. However, retrospective analyses of mergers are often more easily done.

<sup>84</sup> It can sometimes take years to gather the data to do a good study on the likely impacts of a merger.

<sup>85</sup> Many retrospective analyses address the outcome of agency inaction (i.e. mergers that the agencies did not block, but might have been close to the enforcement threshold).

<sup>86</sup> This scorecard is reproduced from tbl. 4, Hahn and Sunstein, *A New Executive Order*, at 1519 (2002).

Table 7. Regulatory Scorecard

Regulatory impact summary	
I. BACKGROUND ON RULE AND AGENCY AGENCY AND DEPARTMENT/OFFICE NAME CONTACT PERSON TITLE OF THE RULE RIN NUMBER TYPE OF RULEMAKING (FINAL/INTERIM/PROPOSED/NOTICE) STATUTORY AUTHORITY FOR THE RULE BRIEF DESCRIPTION OF THE RULE	
TELEPHONE NUMBER	DOCKET NUMBER
TYPE OF RULE (REGULATORY/BUDGET IMPACT)	
MAIN REASON FOR RULEMAKING	
II. OVERALL IMPACT Will the rule have an impact on the economy of \$100 million or more? Yes/No Best estimate of the present value of quantifiable benefits of the rule. \$ _____ Best estimate of the present value of quantifiable costs of the rule. \$ _____ Do the quantifiable benefits exceed the quantifiable costs? Yes/No Report the dollar year of costs and benefits. _____ Report the discount rate used in the calculations for costs and benefits. If more than one discount rate was used in calculations, please explain why. Discuss level of confidence in the benefit-cost estimates and key uncertainties. Include a range for costs and benefits. _____ Identify benefits or costs that were not quantified. _____	

### III. COSTS AND BENEFITS

#### Estimated Incremental Costs

1. Costs and breakdown of quantifiable costs by type.

Annual Years in Which Present Value Costs Occur

Total Costs

Compliance Costs

Administrative Costs

Federal Budget Costs

Local/State Budget Costs

Other Costs

Notes: \_\_\_\_\_

2. Give a brief description of who will bear the costs.

#### Estimated Incremental Benefits

1. Benefits and breakdown of quantifiable benefits by type.

Annual Years in Which Present Value Benefits Occur

Total Benefits

Health Benefits

Pollution Benefits

Other Benefits

Notes: \_\_\_\_\_

2. Give a brief description of who will benefit.

### IV. ALTERNATIVES TO THE REGULATION

List and briefly describe the alternatives to the rule that were considered and why they were rejected, including a summary of costs and benefits of those alternatives. If no alternatives were considered, explain why not.

Source: Based on Table 4 in Robert W. Hahn and Cass R. Sunstein, 'A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis', 150 U. Pa. L. Rev. (2002) 1489, at 1519.

For example, this past year, of the fourteen final major regulations adopted, eight did not have quantified and monetized estimates of both benefits and costs.<sup>87</sup> This is problematic. It is difficult to determine the aggregate net benefits of regulation if more than half of the rule analyses do not provide benefits or costs. We propose that OMB request the agencies to score their own regulatory analyses on a few simple criteria: whether the agency monetized or quantified costs and benefits, used the discount rates prescribed by OMB, and considered alternatives.<sup>88</sup> OMB should summarize the results from the scorecards in its report.

## B. Recommendations for Europe

*Recommendation 1: The European Union should implement a policy specifying that the primary objective of regulation is to maximize net benefits*<sup>89</sup>

One of the key requirements of Executive Order 12,866 is that benefits justify costs.<sup>90</sup> The EU should issue a similar directive. We would prefer language suggesting that net benefits be maximized to the extent permissible by law. We recognize that such a statement is not sufficient for improving regulation, but it is a very good starting point. A harder problem, not addressed here, is the need to develop a regulatory culture that accepts net benefit maximization.

The requirement that net benefits be maximized requires that some kind of benefit-cost analyses be done, at least for major regulations. Cost-effectiveness analysis will not be sufficient in most cases, because it does not provide explicit guidance on the selection of a particular goal or target. Instead it provides an approach for achieving a given objective at the lowest social cost.<sup>91</sup>

While we endorse net benefit maximization as an objective, we hasten to add that a decision-maker may want to consider other factors in a decision. For

<sup>87</sup> See *Informing Regulatory Decisions: Draft Report to Congress on the Costs and Benefits of Federal Regulations*, Office of Management and Budget, at 1 (2004) ('During the past year, 6 'major' final regulations with quantified and monetized benefits and costs were adopted . . . There were an additional 8 final 'major' regulations that did not have quantified and monetized estimates of both benefits and costs.')

<sup>88</sup> For a discussion of alternatives, see Robert Hahn *et al.*, 'Assessing Regulatory Impact with Executive Order 12,866', Harv. J. L. & Pub. Pol'y (2000), 874–75: 'Unfortunately, the agencies generally did not provide a significant analysis of alternatives in RIAs, even when the agencies conducted a quantitative analysis of the preferred option . . . This incomplete assessment of alternatives makes it difficult to assess whether the alternatives would actually be superior to an agency's preferred policy, even when using an agency's own assessment.' See, e.g., Robert Hahn and Patrick Dudley, 'How Well Does the Government Do Cost-Benefit Analysis?' (Washington, D.C.: AEI-Brookings Joint Center, 2004).

<sup>89</sup> We recognize that this recommendation may be difficult to implement due to fears that the sovereignty of member states would be violated.

<sup>90</sup> Executive Order 12,866, §1 (b) 6 states that 'each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.' Executive Order 12291, §2 (b) states that 'regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society.'

<sup>91</sup> See Arrow *et al.*, *Benefit-Cost Principles*, at 6 ('Economic analysis can be useful in designing regulatory strategies that achieve a desired goal at the lowest possible cost.')

example, if a proposed regulation were to result in major inequities, then the distributional aspects of a regulation should also be considered.<sup>92</sup> In addition, a decision-maker will want to make sure that quantitative factors do not crowd out important qualitative factors, and that key uncertainties are considered.<sup>93</sup>

The reason we think maximization of net benefits should be a primary objective of policy is because it will encourage regulators to focus on policies that could improve economic welfare. Although this criterion is not perfect (indeed, no criterion is), it is a good starting point. Furthermore, it could help regulators avoid passing regulations that are not based on sound science, or that benefit special interests at the expense of the public.<sup>94</sup>

We recognize that implementing this recommendation is a big step for the EU. There are many who favor some version of the precautionary principle. In general, we do not endorse the precautionary principle for decision-making for three reasons. First, there is not a single, widely accepted version of the principle.<sup>95</sup> The EU has not clarified which version to use for regulatory decision-making. Instead, it has only provided ambiguous guidance, suggesting that the precautionary principle should be considered within a framework of risk analysis.<sup>96</sup> Stewart identifies four different categories of the precautionary principle, ranging from weak to strong.<sup>97</sup> And Sandin counts no fewer than 19 formulations of the precautionary principle.<sup>98</sup>

<sup>92</sup> See Arrow *et al.*, *Benefit-Cost Principles*, at 8 ('While benefit-cost analysis should focus primarily on the overall relationship between benefits and costs, a good benefit-cost analysis will identify important distributional consequences of a policy . . . Usually, it is better to address concerns about local economic spillover effects of regulation by using tax and transfer policies rather than regulatory policies.')

<sup>93</sup> See Arrow *et al.*, *Benefit-Cost Principles*, at 10 ('Not all impacts of a decision can be quantified or expressed in dollar terms. Care should be taken to assure that quantitative factors do not dominate important qualitative factors in decisionmaking.') See also Arrow *et al.*, *Benefit-Cost Principles*, at 10: 'Benefits and costs of proposed policies should be quantified wherever possible. Best estimates should be presented along with a description of the uncertainties.'

<sup>94</sup> See, for example, Cass Sunstein, *Risk and Reason*, at viii (discussing how people often think poorly about dangers and sometimes fear the wrong things, leading government to make inefficient policy decisions).

<sup>95</sup> See John Graham and Susan Hsia, 'Europe's Precautionary Principle: Promise and Pitfalls', 5 *Journal of Risk Research* (2000) 4, at 380 ('In short, there is no such thing as *the* precautionary principle! In the context of such diverse formulations of the precautionary principle, it is disturbing that the EC Communication does not offer a definition or embrace or adapt an existing definition.')

<sup>96</sup> See European Commission, *Communication from the Commission on the Precautionary Principle*, The Commission of the European Communities (2000), at 13 ('The Commission considers that measures applying the precautionary principle belong in the general framework of risk analysis, and in particular risk management.') See also Scott Farrow, *Using Risk Assessment, Benefit-Cost Analysis, and Real Options to Implement a Precautionary Principle*, 24 *Risk Analysis* (2004) 3 (suggesting that the Precautionary Principle is more a concept for risk management than a replicable guide for action.)

<sup>97</sup> See, e.g., discussion by Richard Stewart, *Environmental Decision-Making under Uncertainty*, 20 *Research in Law and Economics* (2002) 71, 76. Stewart, for example, distinguishes among four different applications of the precautionary principle. See also Jonathan Wiener, *Comparing Precaution in the United States and Europe*, 5(4) *Journal of Risk Research* (2002), at 317–49.

<sup>98</sup> See Per Sandin, 'Dimensions of the Precautionary Principle', 5(5) *Human and Ecological Risk Assessment* (1999) at 889–907. See, e.g., John Graham & Susan Hsia, 'Europe's Precautionary Principle: Promise and Pitfalls', 5(4) *Journal of Risk Research* (2002), at 379, 380.

Second, some applications of the principle can lead to undesirable, or even, perverse results.<sup>99</sup> For example, a regulation banning genetically modified food might increase malnutrition, resulting in several deaths. The precaution taken against risks associated with genetically modified foods could cause even more significant health risks.<sup>100</sup> This approach could paralyze decision-making because it implies taking precautions against both regulating and failing to regulate. A precautionary approach to analyzing costs and benefits of climate change could imply a \$100 tax per ton of carbon emitted, or paralyze policymaking due to a desire to take precautions against both the risks of carbon and the risks of the carbon tax itself.<sup>101</sup>

Third, some versions of the precautionary principle often fail to provide a clear guide for policy analysis. At the most basic level, it is not logically possible to exercise extra precaution in all endeavors if one has a fixed budget constraint, so one has to choose where to exercise more or less precaution. The precautionary principle, in many of its versions, does not provide much help on this important issue.<sup>102</sup> The 1998 Rio definition of the precautionary principle was a modest formulation that covered only those threats that are 'serious or irreversible'. The Wingspread version was more aggressive and covered all 'threats' of harm. Neither of these statements provides guidance on *how much* to regulate given fixed resources.<sup>103</sup>

<sup>99</sup> See John Graham and Susan Hsia, 'Europe's Precautionary Principle: Promise and Pitfalls', 5(4) *Journal of Risk Research* (2002), at 371–90 (arguing that there are some pitfalls in the European Commission's approach to applying the precautionary principle.)

<sup>100</sup> See Cass Sunstein, *Risk and Reason*, at 104 ('A failure to allow genetic modification might well result in many deaths, and a small probability of many more. Hence the precautionary principle seems to argue both for and against banning genetic modification of food.') See also John Graham and Susan Hsia, 'Europe's Precautionary Principle: Promise and Pitfalls', 5(4) *Journal of Risk Research* (2002), at 371–90 (providing additional examples of the perverse consequences, or 'risk tradeoffs', of applying the precautionary principle.) See, e.g., Jonathan Wiener, 'Managing the Iatrogenic Risks of Risk Management', 9 *Risk: Health, Safety and Environment* (1998), at 39–82.

<sup>101</sup> See Robert Hahn, *The Economic Analysis of Regulation: A Response to the Critics*, 71(3) *U. Chic. L. Rev.* 3 (2004), at 1050–51 (arguing against Ackerman and Heinzerling's 'holistic' and precautionary approaches to regulatory analysis.) See also Sunstein, *Risk and Reason*, at 103. ('In real-world controversies, a failure to regulate will run afoul of the precautionary principle because potential risks are involved. But regulation itself will cause potential risks, and hence run afoul of the precautionary principle too; and the same is true for every step in between. Hence the precautionary principle, taken for all that it is worth, is literally paralyzing. It bans every step, including inaction itself.')

<sup>102</sup> See, e.g., Principle 15 of the 1992 UN Rio Declaration on Environment and Development ('In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'). See also the 1998 Wingspread Declaration, reprinted in Carolyn Raffensperger and Joel Tickner, *Protecting Public Health and the Environment* (1999) ('When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.')

<sup>103</sup> They do not, for example, help in setting the standard for particulate matter. See Robert Hahn, *The Economic Analysis of Regulation: A Response to the Critics*, 71(3) *U. Chic. L. Rev.* (2004), at 1050–51 for a discussion of the problems that can arise when one uses a 'holistic' approach to regulation.

Although we think the so-called precautionary principle has some clear defects, we also believe that valuable aspects of versions of the precautionary principle can be embedded within a utilitarian framework, and thus be used in a standard benefit-cost analysis. For example, problems characterized by irreversibilities – such as the persistence of certain chemicals in the atmosphere that deplete the ozone layer – can be modeled using standard techniques in benefit-cost analysis.<sup>104</sup>

While we would expect some groups to oppose our recommendation, there are forces within the European Union that may make benefit-cost analysis more palatable. These include the growing regulatory burden that results from inflexible regulation in labor and product markets and the fiscal discipline that may be imposed by the adoption of the euro. Even if adoption of a principle of maximizing net benefits were not feasible at this point, it would still be desirable to do cost-effectiveness analysis.<sup>105</sup> If the US experience is any guide, it appears that cost-effectiveness analysis can be quite helpful in improving the design of specific regulations.

*Recommendation 2: The EU should create a strong centralized regulatory oversight unit to help evaluate significant regulatory proposals. In addition, states that do not have such units should consider creating them*

Some scholars in Europe have recommended that the EU establish a central unit officially responsible for maintaining the quality of RIAs.<sup>106</sup> A centralized oversight unit can help improve the quality of regulatory impact analyses. We would go further and emphasize that this central unit must be independent of regulatory agencies that are charged with implementing the regulations, and it should have some real decision-making authority. In the best of all possible circumstances, we think this unit should have a status similar to the agencies it will have to discipline.<sup>107</sup>

<sup>104</sup> See, for example, Kenneth Arrow and Anthony Fisher, 'Environmental Preservation, Uncertainty, and Irreversibility', 88(2) Quart. J. of Econ. (1974), at 312–19 for an early treatment of irreversibility, and Avinash Dixit and Robert Pindyck, *Investment Under Uncertainty* (Princeton, 1994) for a more general discussion. For an insightful analysis of how various concepts associated with the precautionary principle can be applied within a standard economic framework, see Scott Farrow, *Using Risk Assessment, Benefit-Cost Analysis, and Real Options to Implement a Precautionary Principle*, 24 Risk Analysis 3 (2004).

<sup>105</sup> Unlike benefit-cost analysis, however, cost-effectiveness analysis does not provide a measure of the value of the activity. Instead it provides an approach for achieving a given objective at the lowest social cost. See, e.g., Robert Hahn and Robert Litan, *A Review of the Office of Management and Budget's Draft Guidelines for Conducting Regulatory Analyses*, Washington DC: AEI-Brookings Joint Center (2003) ('We think that cost-effectiveness analysis is useful, but unduly restrictive, when the goal of the policy is not prescribed by regulation or legislation.') See also Frank Vibert, *The EU's New System of Regulatory Impact Assessment – A Scorecard*, European Policy Forum (2004) (arguing that cost effectiveness could be very helpful in the EU context.)

<sup>106</sup> According to Radaelli, the EU does not have a central body for quality control and monitoring of the RIA process. See Claudio Radaelli, *Diffusion of Regulatory Impact Analysis* (2004), tbl. 2, at 734. This centralized oversight unit need not be a new agency, but can be placed in a body accountable to the Presidency of the European Commission, such as the General Secretariat.

<sup>107</sup> A unit with recognized authority, such as the US regulatory oversight office, represents an important first step, and may be adequate for purposes of effective oversight.

This unit should play a leadership role in establishing information quality and economic guidelines for proper regulatory analysis in the EU and member states.<sup>108</sup> The unit should review all major regulations implemented at the EU level and have the ability to accept, reject, or improve upon them. For example, if a regulation has net costs, the central unit should have the authority to reject the regulation or ask the regulatory agency to revise it. After reviewing regulations, the central unit should publish its findings and make them available on the Internet.<sup>109</sup>

It is important to keep in mind that this central structure may face political resistance from member states because they may have different regulatory objectives.<sup>110</sup> Therefore, a centralized EU oversight unit should apply only for regulatory proposals at the EU level, and should not interfere with regulations passed by member states. The member states should have their own centralized oversight units that monitor the effectiveness of their regulations.<sup>111</sup>

Different member states, for example, use RIAs for different purposes. Radaelli suggests that in the United Kingdom, the RIA was used as a solution to the problem of 'rolling the state back', and in Germany, it is an instrument geared towards the general aim of simplification.<sup>112</sup> While the EU should defer to states on state-based regulation, it could play a similar role to the US oversight unit in terms of defining guidelines for good economic analysis, risk assessment, and data quality that the states could choose to use.<sup>113</sup>

In addition, we think it would be useful for the central unit to do an annual report on the benefits and costs of EU regulation that is similar to the OMB

<sup>108</sup> For useful examples, see U.S. OMB *Guidelines for the Conduct of Regulatory Analyses* (2002) and OMB's *Information Quality Guidelines* (2002).

<sup>109</sup> RIAs are not currently published on the Internet. Some scholars recommend that the Commission publish 'Intermediate' and 'Final' RIAs, along with supporting analyses, key submissions by stakeholders and Commission responses. See Bruce Ballantine, *Improving the Quality* (2001). See also Lorenzo Allio, Bruce Ballantine, and Dirk Hudig, *Achieving a New Regulatory Culture in the European Union: An Action Plan*, European Policy Centre (2004).

<sup>110</sup> See Claudio Radaelli, *Diffusion of Regulatory Impact Analysis* (2004), at 739. (arguing that different member states use RIAs for different purposes, and therefore, there are several problems that can arise when policymakers from one nation try to import regulatory oversight lessons from another).

<sup>111</sup> In the US, state regulatory oversight units generally vary in terms of their objectives and their impact, and not all states have such units. See, e.g., Robert Hahn, 'State and Federal Regulatory Reform: A Comparative Analysis', 29(2) *Journal of Legal Studies* (2000), at 873–912.

<sup>112</sup> See Claudio Radaelli, *Diffusion of Regulatory Impact Analysis*, at 739. Radaelli also contrasts the use of RIA between the Netherlands and Denmark. He suggests that in Denmark, 'consensus-building' is preferred to holding the decision-maker accountable to rigorous empirical assessments. Due to this consensus-building objective, quality control of RIA process tends to be decentralized and only partial estimates of benefits and costs are provided, making trade-offs and compromise always possible. In the Netherlands, on the other hand, RIA has been used to 'break the cosy relationships between administration, unions, and employers and to bring back into the policy process the wider perspective of the ordinary citizen, small firms, and other stakeholders.'

<sup>113</sup> See OMB 2003 Report on guidelines for conducting regulatory analysis and OMB (2003b) for information quality guidelines.



annual report, but targeted to the EU. This report should focus on summarizing and evaluating recent regulations in the EU.

Finally, the unit must be adequately funded in order to provide training to EU regulators and better information to members of the European Parliament. If funding is a significant constraint, then the responsibilities of the agency should be pared back accordingly. We think the most important task the agency needs to accomplish is to provide a high-quality review for major regulations.

This model of regulatory oversight assumes that the analysis itself is done or overseen by the implementing agency. This means that the implementing agency will need a strong capability in policy analysis, economics, and other disciplines where appropriate. Ideally, the regulatory analysis done by the implementing agency should be done by an *independent* unit within the implementing agency.

We recognize that the expertise may not reside in such agencies now. There are several options. One possibility is for the centralized oversight authority to be given a budget that allows it to commission studies of regulations from experts. These experts could reside in consulting firms, think tanks, or universities, for example.<sup>114</sup> It would be the job of the regulatory oversight agency to review these analyses and ensure their quality.<sup>115</sup>

An alternative model would be for the centralized unit to do the analysis itself, and not serve as a reviewer of other analyses. We think that such a model is worth considering both in the EU and the US. It would require greater resources for the centralized oversight unit. Moreover, the agency would no longer serve an oversight role, per se, but rather one of providing unbiased economic analysis of regulatory proposals.

There are numerous issues that would need to be addressed in designing such an agency. These include avoiding capture, political placement, and design. These issues, by and large, are beyond the scope of this paper. We simply wish to point out there is a need for an effective federal oversight mechanism, in our view, if federal regulations are expected to have a significant impact on the member states' economies.

*Recommendation 3: The EU, as well as each member state, should create a structure that is balanced, which promotes efficient regulation and discourages inefficient or ineffective regulation*<sup>116</sup>

The EU and member states should create centralized structures that are neither pro-regulatory nor anti-regulatory and that attempt to quantify all benefits and

<sup>114</sup> In the US, some think tanks, such as the AEI-Brookings Joint Center, do analyses that inform the regulatory debate. These analyses serve to complement the government's analysis of its own regulations, and, on occasion, give rise to the consideration of options that the regulators may have missed or did not analyze well.

<sup>115</sup> Perceptions also matter here. One would not, for example, want to give an analysis of an automobile industry regulation to the automobile industry. At the same time, one would almost certainly want to rely on data from the automobile industry in analyzing the proposed regulation.

<sup>116</sup> The purpose of the prompt letter is to suggest an issue that OMB believes is worthy of agency priority. Rather than being sent in response to the agency's submission of a draft rule for OIRA review, a 'prompt'

costs of relevant regulations. Because some EU states focus exclusively on costs in their RIAs, they may be seen as anti-regulatory.<sup>117</sup> While benefits may be more difficult to quantify in some instances, economically efficient policies cannot be identified without considering both costs and benefits.

The EU's central oversight structure, as well as those of the member states, should have transparent procedures for returning or rejecting regulatory proposals. The EU has taken some initial steps in this direction. The Dutch Presidency of the EU, for example, has asked Member States to indicate a number of policy areas that have proven to be inefficiently regulated at the state level. The Presidency's goal is to gather the information, filter it, and finally produce a list of regulations for which new impact assessments and simplification should be a priority. The list should be submitted to the Council of Ministers and European Commission late in October.<sup>118</sup>

The EU should also specify the reasons a proposed regulation is returned, and the kinds of analysis that may be needed to either improve the regulation or provide a sound economic basis for the regulation. When a regulation is rejected, the reasons should be clearly stated.<sup>119</sup>

As noted above, OMB initiated a procedure for encouraging regulations to be implemented in certain areas through the use of prompt letters. A centralized regulatory oversight agency in the EU and in each member state should consider using this mechanism as well. It has the advantage that it shows the oversight agency is interested in regulations that can improve economic efficiency.

One final mechanism the oversight agency can use for improving regulations is to solicit suggestions from the public for improving regulation that are

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letter is sent on OMB's initiative and contains a suggestion for how the agency could improve its regulations. See OIRA website at [http://www.whitehouse.gov/omb/inforeg/prompt\\_letter.html](http://www.whitehouse.gov/omb/inforeg/prompt_letter.html). For a definition of return letter, see [http://www.whitehouse.gov/omb/inforeg/return\\_letter.html](http://www.whitehouse.gov/omb/inforeg/return_letter.html). ('During the course of OIRA's review of a draft regulation, the Administrator may decide to send a letter to the agency that returns the rule for reconsideration. Such a return may occur if the quality of the agency's analyses are inadequate . . . Such a return does not necessarily imply that either OIRA or OMB is opposed to the draft rule. Rather, the return letter explains why OIRA believes that the rulemaking would benefit from further consideration by the agency.')

<sup>117</sup> See *International Study* (2003). UK conducts CBA and measures both benefits and costs, but Norway, Germany, Netherlands, Sweden, and Denmark measure only costs not benefits. See also OECD 1997 table.

<sup>118</sup> See *Reducing the Regulatory Burden: The Arrival of Meaningful Regulatory Impact Analyses*, European Policy Forum (July 2004). 'The Dutch presidency of the European Union offers a further opportunity to campaign for significant progress. Not only does the Dutch government already have a body, ACTAL, which has an official position in reviewing and limiting administrative burdens but the government has also set a 25% target for the reduction of the administrative burden on firms. The Dutch government has indicated that it will organise a high level conference on better regulation in Rotterdam in September 2004 with particular attention to elements of the Commission's action plan on simplifying and improving the regulatory environment.'

<sup>119</sup> The US specifies the reasons that a regulation was returned in return letters. For examples of return letters, see [http://www.whitehouse.gov/omb/inforeg/return\\_letter.html](http://www.whitehouse.gov/omb/inforeg/return_letter.html)

based on sound economics and science. These could include suggestions for adding, eliminating or reforming regulations. Reporting on recommendations from interested parties helps avoid some difficult political issues associated with having the oversight agency make specific recommendations for reform. We suspect this is why the US regulatory oversight authorities may have adopted this approach.

## CONCLUSION

Several countries are showing greater interest in introducing new approaches that will allow them to improve their assessment of regulatory activity.<sup>120</sup> This paper explores regulatory oversight in the United States and Europe and provides recommendations for both places. Six US government reports on the costs and benefits of regulation now have been completed. We offered a critical evaluation of these reports using an approach that scores the reports on various dimensions.

On the positive side, each report provides useful information on the costs and benefits of regulation and the regulatory process. In addition, the reports show how the regulatory oversight function in the US has changed in a relatively short period of time.

On the negative side, there are clear limits to how far an agency like OMB can go in providing an objective critique of sister agencies. One of the telling findings of our analysis is that OMB has taken its sister agencies' analyses of regulations as the basic point of departure for providing information in all of its reports, although OMB has also used its annual report as a place to discuss shortcomings in agencies' analyses.<sup>121</sup> With well-known defects in many of these analyses, we think the degree to which OMB treats agency numbers as reliable is problematic.

The basic problem that an agency like OMB faces in reporting on regulatory policy and developing more effective regulatory policy is that it operates in an intensely political environment. Some of the recent innovations by OMB, such as prompt letters, represent useful ways of addressing the politics and the economics of improving regulation. In that regard, we think that OMB's move to organize agencies to work on information quality guidelines was a good one.<sup>122</sup>

A key insight for those interested in political economy is that strategic use of the administrative process can result in policies that would generally be viewed as

<sup>120</sup> See Regulatory Reform, Documentation, OECD, *available at* [http://www.oecd.org/topic/0,2686,en\\_2649\\_37421\\_1774889\\_1\\_1\\_1\\_37421,00.html](http://www.oecd.org/topic/0,2686,en_2649_37421_1774889_1_1_1_37421,00.html) (last visited 30 July 2003) (listing the regulatory reform documentation from the Organization for Economic Cooperation and Development).

<sup>121</sup> See, e.g., OMB's discussion of the EPA's Section 812 Retrospective Report, OMB 2000 Report to Congress, § II. A. 1 at 20.

<sup>122</sup> See OMB 2002 Report, at 25 (encouraging agencies to commission the National Research Council of the National Academy of Sciences to assist agencies in the development of information quality guidelines).

enhancing efficiency and transparency. Our recommendations for both the European Union and the US are offered in that spirit. We suggest that the EU embrace a model with strong centralized regulatory oversight. We also believe that the model should promote transparency and accountability and be grounded in economics, and build on some of the successes of the US model. We are under no illusions that making the changes we recommend in Europe will be easy. But we think the potential returns to imposing economic discipline on the current regulatory process in the EU and member states could be significant.

Our recommendations for the United States are essentially to broaden the scope of regulatory review and do a better job of providing an honest assessment of the quality of regulations. We think the efforts that the US has made on establishing guidelines are laudable, but only if the guidelines are actually followed by the agencies.

Regulatory oversight in a democratic system is likely to continue to be a challenge for the foreseeable future. Regulation is frequently the domain of special interests, who have a lot to gain from shaping the outcome. In contrast, most consumers and voters do not have an appreciation of this frequently arcane system because it is not in their interest to do so. We believe a good oversight system should attempt to serve as a voice for consumers and citizens, and help to mute the voices of special interests where they do not enhance general economic well-being.