
# EUROPEAN RISK FORUM – POLICY NOTE 17

# COST EFFECTIVENESS ANALYSIS AND THE MANAGEMENT OF RISK

**2010**

**EUROPEAN RISK FORUM**

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of the risk management issues at EU-level.

In order to achieve this, the Forum applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

The Forum believes that:

- High quality risk management decisions should take place within a structured framework that emphasises a rigorous and comprehensive understanding of the need for public policy action (risk assessment), and a transparent assessment of the workability, effectiveness, cost, benefits, and legitimacy of different policy options (risk management).

- Risk management decision-making processes should ensure that outcomes are capable of meeting agreed social objectives in a proportionate manner;

- Risk management decisions should minimise negative, unintended consequences (such as new, unintended risks, economic losses, reduced personal freedoms, or restrictions on consumer choice);

- The way in which risk management decisions are made should be structured, consistent, non-discriminatory, predictable, open, transparent, evidence-based, legitimate, accountable, and, over time, subject to review.

Achieving these goals is, the Forum believes, likely to require extensive use of evidence (especially science); rigorous definition of policy objectives; clear and comprehensive description and assessment of problems and their underlying causes; realistic understanding of the costs and benefits of policy options; and, extensive consultation.

The Forum works with all of the EU's institutions to promote ideas and debate. Original research is produced and is made widely available to opinion-formers and policy-makers at EU-level. As an expert group, the Forum brings together multiple sources of evidence (such as the experience of practioners and policy-makers; non-EU good practices; and academic research) to assess issues and to identify new ideas. Indeed, direct engagement with opinion-formers and policy-makers, using an extensive programme of conferences, lunches, and roundtables, is a feature of the Forum's work.

The ERF is supported principally by the private sector. The ERF does not seek to promote any specific set of values, ideologies, or interests. Instead it considers high quality risk assessment and risk management decisions as being in the public interest. An advisory group of leading academics supports the ERF's work.

Rue de la Loi 227, B – 1040 Brussels, Belgium
Telephone + 32 2 613 28 28 Facsimile + 32 2 613 28 29
www.riskforum.eu email: info@riskforum.eu

## EXECUTIVE SUMMARY

Cost Effectiveness Analysis (CEA) provides a structured framework for helping regulators to compare the quantified benefits of policy actions with their costs. Used well, CEA forces policy-makers and regulators to quantify rigorously the health or environmental benefits of prospective government actions to reduce risks. When properly constructed, CEA provides clear metrics for decision-makers, facilitating comparisons between different ways of managing the same problem, such as reducing risks to human health or public safety. CEA data, derived from a range of risk management actions, can also play a major role in the governance of risk, helping to identify the most efficient ways in which resources can be used to save or improve lives.

CEA is most often used as part of a structured process for making legislative or regulatory decisions. In many leading countries within the OECD area, it is widely used when policy-makers and regulators examine ways of reducing risks to human health or public safety. It focuses on the ultimate outcomes, such as lives saved or improved, rather than intermediate reductions in emissions or exposures. It helps to inform ex ante impact assessment, facilitating the selection of policy options. It provides policy-makers, moreover, with an important analytical tool when benefits are difficult to monetize or when there are barriers to placing values on health or environmental benefits.

Since 2002, the Commission has begun the process of encouraging regulators to make greater use of modern forms of CEA. More needs to be done to build on this and to require greater use of CEA, so as to improve the quality of risk management decisions and of risk governance at EU-level. Specific improvements could include:

- Make it mandatory for all EU-level Impact Assessments of measures designed to manage risks to health; safety, or the environment to be supported by a full CEA;

- Revise the IA guidelines to establish clear tests of cost effectiveness to demonstrate that proposed interventions do more good than harm;

- Recognise within the impact assessment process the need to base estimates of the benefits of risk management decisions on the weight-of-scientific evidence;

- Require IA reports to include comparative cost effectiveness analyses;

- Require the IAB to verify that the benefits of regulatory proposals are fully identified, credible, measurable, and capable of being assessed on an ex post basis;

- Use CEA as part of an extensive ex post evaluation of risk management policies designed to protect health, safety, and the environment

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## 1. BACKGROUND

Cost Effectiveness Analysis (CEA) provides a structured framework for helping regulators to compare the quantified benefits of policy actions with their costs. Used well, CEA forces policy-makers and regulators to quantify rigorously the health or environmental benefits of prospective government actions to reduce risks. When properly constructed, CEA provides clear metrics for decision-makers, facilitating comparisons between different ways of managing the same problem, such as reducing risks to human health or public safety.

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In the past, the extent of use of CEA has been limited by a range of technical and ethical problems. Some commentators have raised concerns, for instance, about quantifying improvements to mortality or morbidity rates. In other instances, it has proven difficult to identify and quantify health benefits that occur in future time periods. There have also been problems with ensuring that the costs of government action are accounted for fully, especially indirect impacts on economic efficiency and productivity. However, extensive research[1], and widespread use of CEA in a number of OCED countries, has helped overcome many of these problems.

Today, the use of CEA, supported by modern methodologies, as a tool to help manage risks helps improve the quality of regulatory decisions in a number of important ways:

- It demonstrates clearly the linkages between policy action and outcomes, strengthening credibility and legitimacy;

- It illustrates to all stakeholders how the benefits of policy actions justify the costs, developing transparency and building support for effective implementation;

- It improves the rigour with which officials identify and assess the benefits of public policy actions, improving the evidence base for decision-making;

- It focuses on risks rather than hazards, facilitating proportionate management of potential harms;

[1] See for example, Viscusi K.P. *'Monetizeing the Benefits of Risk and Environmental Regulations'* (AEI Brookings Working Paper 06-09, 2006); Viscusi K.P. *'Regulation of Health, Safety, and Environmental Risks'* (AEI Brookings Working Paper 06-11, 2006), and Graham J.D. *'Saving Lives Through Administrative Law and Economics'* (University of Pennsylvania Law Review, Vol. 157, 2009)

- It provides a transparent and tangible basis for effective ex post evaluation of regulatory decisions, creating accountability; and,

- It facilitates the objective and rational comparison of policy options, improving the net benefits of government action.

## 2. COST EFFECTIVENESS ANALYSIS AND RISK GOVERNANCE

Risk governance encompasses the selection of risks to be managed by government action; the objectives of risk management policy; the level of social acceptance of risk; the way in which risks should be managed; and, the processes by which risk management decisions are made. Data from a wide range of CEAs can help policy-makers make more informed choices about which risks to regulate and how to control, mitigate, or eliminate them.

An example of this policy-based of use of CEA data can be found in research undertaken by the US Office of Management and Budget (OMB) between 1967 and 2005. This provides a ground-breaking analysis that has helped shape the way in which US regulatory agencies think about the cost effectiveness of regulation and the governance of risk[2]. It also provides useful insights for the future management of risk at EU-level.

Based on regulatory impact analyses (RIAs) submitted by Federal regulatory agencies, OMB researchers examined nearly 80 regulatory interventions designed to protect citizens from risks to public safety and human health. After extensive analysis of the RIA submissions, researchers identified a number of major risk governance issues, including:

- There was an enormous difference in the cost effectiveness of regulatory interventions aimed at reducing safety, cardiovascular, and cancer risks in the USA. Measured in terms of cost per life saved, the costs of regulations varied between $0.1 million and $72 billion.

- Other measures of regulatory efficiency produced equally wide outcomes. More than two-thirds of the interventions failed a benefit-cost test based on a valuation of $7 million per statistical life saved, for example.

- Regulations aimed at the control of narrowly-defined specific toxic substances (principally to avoid cancers) were significantly less cost-effective than safety regulations. Moreover, many of the interventions designed to reduce the risk of cancer posed by exposure to 'toxics' failed additional tests of costs and benefits, if the value of lives saved was quantified.

- Retrospective analysis of safety regulations revealed a tendency by regulatory agencies to overestimate projected benefits. In part, this was because US regulatory agencies often made use of "worst case" assumptions, upper bound

[2] See for example, Morrall J. *'A Review of the Record'* (Regulation, Vol. 10, 1986); Morrall J. *'Saving Lives: A Review of the Record'* (a working paper for the AEI-Brookings Joint Centre for Regulatory Studies, July 2003); and Morrall J '*OMB Circular A-4 Regulatory Guidance Analysis'* (presentation to the European Policy Centre, 2006)

estimates, and conservative default assumptions rather than expected values based on the "weight of evidence". Guidelines from the OMB, developed since 2003, have tried to change these methods.

- New tools have been designed to provide additional ways of assessing the effectiveness of risk-based regulations. Research in the USA has identified the wider impacts on human health of the diversion of economic resources to protect against technological risks to public safety, human health, and the environment[3]. It is suggested that the diversion of resources equal to $21 million induces one additional fatality. It is argued that this happens because of the impact of lower income levels on the behaviour of certain groups (deprivation impacts, for example) and because some diverted resources would otherwise have been used to reduce risks in the absence of regulation. This is described as *"health-health analysis"*. Applying this analytical technique, researchers revealed that in a number of instances, principally regulations designed at lowering the cancer risk posed by specific hazardous substances, government intervention may have done more harm than good.

- Regulators had ignored additional regulatory interventions that could save significant numbers of lives at relatively low cost, if implemented.

- CEA provides regulators with a tool for assessing and identifying the most effective way to save lives across a wide range of policy areas, facilitating a greater and more rational focus of public policy action on substantial risks rather than perceived hazards or 'popular' risks.

The OMB analyses highlight the value, for decision-makers, citizens, and officials, of using cost effectiveness tools to measure the potential impacts of proposed government action. For measures designed to manage risks to human health and public safety, CEA overcomes the need to monetise the value of lives (or improved) saved whilst, at the same time, providing a clear link between the principal purpose of the legislation and the economic cost. Rather than focusing on the monetary valuation of statistical lives saved or improved, CEA is able to use quantitative improvements in lives saved, longevity, and other similar measures. This approach also allows decision-makers to develop rankings of regulatory options, and to compare new proposals with previous activity.

Alongside this, the work of the OMB highlights the importance of guidelines to ensure that scientific input into regulatory decision-making is properly structured. Other research suggests that there is a tendency for EU scientific committees, comitology committees, and regulators to be swayed by worst case analyses rather than expected values based on the weight-of-evidence approach. As a result, potential harms are exaggerated, along with the potential benefits of reducing them.

The OMB's work also makes an important contribution to the development of improved future impact analysis tools at EU-level. The *"Health-Health Analysis"* is a new, and little understood development. It provides officials with a way of highlighting some of the unintended consequences of proposed risk management measures, and can be used to

[3] Lutter R. and Morrall J. *'Health-Health Analysis: A New Way to Evaluate Health and Safety Regulation'* (Journal of Risk and Uncertainty, Vol.. 8, 1994) and Viscusi K. *'Mortality Effects of Regulatory Costs and Policy Evaluation Criteria'* (RAND Journal of Economics, Vol 25, 1974)

warn decision-makers of the possibility that government intervention may do more harm than good. As Impact Assessment (IA) guidelines are improved at EU-level, new mechanisms of analysis of regulatory efficiency could be considered.

Finally, the OMB's overall analysis of the cost-effectiveness of different types of regulation has particular relevance for the future management by the EU of threats to public safety, human health, and the environment posed by the production and use of toxic substances. New regulatory approaches used by the EU, such as those embedded within REACH, attempt to manage specific toxins on the basis primarily of hazard characteristics. On the basis of the evidence from the USA, an environment of advanced controls over regulatory interventions, some of the decisions that will be made under these new legislative frameworks could represent poor 'value' for society. In many cases, benefits may not justify costs. The resources consumed could be better spent elsewhere and may, in some cases, induce more fatalities than they save.

## 3. EU INSTITUTIONS AND COST EFFECTIVENESS ANALYSIS

Simple cost effectiveness tools have played a role in regulatory management at EU-level for over twenty years. They have been used as a part of the technical decision-making processes used to set Emission Limits for pollutants and Occupational Exposure Limits for the exposure of workers to toxic substances, for example. Within these policy areas, cost effectiveness tools have been used to assess the private sector costs (measured in terms of marginal expenditures on protective equipment, abatement facilities, treatment plants, and medical monitoring) needed to reduce pollution or exposure to hazards by quantifiable amounts. In some instances, they have provided the data to construct diagrammatical representations of the marginal and cumulative costs of achieving additional reductions in potential hazards. Such analyses have helped policy-makers identify disproportionate increases in costs, providing a framework for establishing economic limits on hazard reduction expenditures.

This is, however, an incomplete and old-fashioned use of cost effectiveness analysis. It fails to consider the ultimate outcomes of government interventions, and uses hazard (the possibility of harm) as a proxy measure of risk (the likelihood, extent, and impact of harm). As a result, it fails to provide policy-makers with a clear understanding of the costs of achieving additional improvements in mortality, morbidity, or environmental protection. In some cases this may lead to insufficient protective action being taken, in others too much may be required.

In contrast, modern CEA requires officials to focus on risk, identifying and quantifying likely changes in mortality, morbidity, or the environment, rather than on quantifying reductions in pollutants or exposures.

Since the introduction of its integrated Impact Assessment (IA) system in 2002, the European Commission has begun to promote the use of modern forms of CEA as tools for assessing the costs and benefits of legislative proposals. In the most recent revision to the Commission's IA guidelines, issued in 2009, officials are encouraged to use CEA as one of the ways in which policy options can be compared, prior to determining the precise form of government intervention. In support of this, the Commission provides officials with details of potential CEA methodologies.

Whilst the Commission's encouragement of the use of CEA as a decision-support tool within the ex ante assessment of prospective risk management rules is to be welcomed, there are a number of problems:

- Unlike the situation in the USA, the use of CEA to assess measures designed to reduce health or safety risks is not mandatory. For US regulators, OMB Circular A-4, first issued in 2003, requires CEA, alongside other measures, including monetization for benefits, to be used for all regulations that seek to cut safety or health risks, and it is the primary measure of benefit-cost if such measures are targeted at children.

- A further problem is the systemic lack of quantification of benefits of government intervention included in Commission IA reports identified by the Commission's Impact Assessment Board (in 2008, 2009, and 2010) and by the European Court of Auditors (in 2010). Without widespread use of quantification, CEA tools are ineffective.

- The EU's approach to the use of CEA tools suffers from other additional weaknesses. For instance, the Commission's IA guidance notes do not require officials to make use of "health-health analysis" or other tools (such as valuing statistical lives saved) to establish whether proposed risk management measures do more good than harm. Alongside this, scientific advisers and decision-makers are not required to make use of expected values based on the weight-of-evidence approach (as opposed to worst case analyses) when quantifying potential harms[4]. This leads to the benefits of government intervention being over-stated and encourages the use of high cost risk management strategies.

## 4. RECOMMENDATIONS

Modern Cost Effectiveness Analysis provides decision-makers with important insights into the extent to which the benefits of risk management measures justify their costs. It creates strong incentives for rigorous analysis for benefits; it focuses on risks rather than hazards; it provides a credible baseline for ex post evaluation; and it encourages decision-makers to select policy options that deliver proportionate improvements in mortality, morbidity, or environmental quality. Over time, moreover, data from CEAs helps inform risk governance processes, improving the selection of risks to be regulated.

Over the last eight years, the Commission has begun the process of encouraging regulators to make greater use of modern forms of CEA. More needs to be done to build on this and to require greater use of CEA, so as to improve the quality of risk management decisions and of risk governance at EU-level. Specific improvements could include:

[4] Estimates of potential harms based on "worst case scenarios" have two weaknesses: first, they may be based on hypothetical exposures rather than expected handling and use; and, second, they tend to overstate the potential for harm. Both of these tendencies lead to potential harms being exaggerated, inflating the potential benefits of harm reduction. This distorts cost-benefit analyses, reducing the quality of regulatory decisions. In some cases, this leads to the selection of disproportionate risk management options, for instance.

- **Make it mandatory for all EU-level Impact Assessments of measures designed to manage risks to health; safety, or the environment to be supported by a full CEA,** improving the formal review of policy options;

- **Revise the IA guidelines to establish clear tests of cost effectiveness to demonstrate that proposed interventions do more good than harm,** developing appropriate methodologies and processes for the monetization of benefits and of the "health-health analysis";

- **Recognise within the impact assessment process the need to base estimates of the benefits of risk management decisions on the weight-of-scientific evidence,** avoiding over-claiming through worst case scenarios;

- **Require IA reports to include comparative cost effectiveness analyses that examine other interventions,** highlighting the relative costs of achieving improvements in mortality, morbidity, or the environment;

- **Require the IAB to verify that the benefits of regulatory proposals are fully identified, credible, measurable, and capable of being assessed on an ex post basis,** creating a formal 'hurdle' before a regulatory proposal is allowed to be considered by the Commission;

- **Use CEA as part of an extensive ex post evaluation of risk management policies designed to protect health, safety, and the environment,** improving the basis for future decision-making and informing the development of risk governance policies

## 2010

**This policy brief was written by Richard Meads, the European Risk Forum's rapporteur, with help from members of the Forum. However, the views and opinions expressed in this paper do not necessarily state or reflect those of the European Risk Forum.**

Rue de la Loi 227, B – 1040 Brussels, Belgium
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