



COST EFFECTIVENESS ANALYSIS AND RISK MANAGEMENT DECISION-MAKING

HIGHLIGHTS NOTE 11

Cost Effectiveness Analysis (CEA), when used well, is one of the most important decision support tools used to inform ex ante and ex post assessments of measures to manage risks. It focuses on the ultimate outcomes of risk management decisions.

CEA is of particular value when regulators need to make large numbers of case-by-case decisions to implement ambitious risk management laws using the mechanisms of the Administrative State. It helps highlight disproportionate regulatory choices, forces a more rigorous understanding of benefits, requires costs to be identified fully, makes the use of precaution transparent, and improves the design of implementation measures.

This ERF Highlights Note provides a description of CEA and the sets out ways in which its use can improve the quality of regulatory decisions. It highlights the importance of using CEA to overcome weaknesses in the processes implementing risk management measures at EU-level (and used by the “EU Administrative State” – see below). It examines current guidance for the use of CEA at EU-level, and concludes with a brief list of suggested reforms.

COST EFFECTIVENESS ANALYSIS

Cost Effectiveness Analysis (CEA) provides a structured framework for helping regulators to compare the quantified benefits of legislative or regulatory decisions 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. It provides clear metrics for decision-makers, facilitating comparisons between different ways of managing the same problem, such as reducing risks to human health, public safety, or the natural world.

CEA focuses on the ultimate outcomes of risk management decisions, such as number of lives

saved or improved, longevity, reductions in premature death and other similar measures, rather than intermediate reductions in emissions or exposures. Unlike Cost Benefit Analysis, which requires a monetary valuation of both benefits and costs, **CEA facilitates outcomes-based quantitative metrics.**

BENEFITS

Widely used throughout the OECD area, CEA is one of the most important regulatory management tools used to improve the quality of risk management decisions:

- **It demonstrates clearly the linkages between policy action and its ultimate 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 ultimate benefits of public policy actions,** improving the evidence base for decision-making;
- **It focuses on risks rather than hazards,** thereby requiring regulators to identify fully the potential benefits, through reduction of harms, of government interventions;
- **It facilitates proportionate management of potential harms;**
- **It provides a transparent and tangible basis for effective ex post evaluation** of regulatory decisions, creating accountability;

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

- **It can play a major role in the governance of risk**, using CEA data, derived from a range of risk management actions, to help identify the most efficient ways in which resources can be used to save or improve lives.

Evidence from research by US regulators and scholars highlights the value of CEA for improving the quality of regulatory decision-making.

Studies found that there was an enormous difference in the cost effectiveness of regulatory interventions aimed at reducing health risks, and that regulations aimed at the control of narrowly-defined toxic substances were the least cost effective. There was also evidence, from retrospective analyses, that regulators often over-estimated projected benefits, in part by the use of "worst case" assumptions, upper bound estimates, and over-conservative default assumptions. Finally, researchers found that regulators had ignored additional regulatory interventions that could, if implemented, save significant numbers of lives at relatively low cost.

On the other hand, it is important to complement CEA analyses, where this is reasonably possible, with an understanding of distributional effects of benefits and costs across groups affected.

CEA AND THE ADMINISTRATIVE STATE

CEA is of particular value when regulators need to make large numbers of case-by-case decisions to implement ambitious risk management laws using the mechanisms of the Administrative State.

At EU-level, there is evidence of important failings of the processes used to assess evidence and to prepare implementation measures. Whilst many implementation measures are of good quality, on too many occasions proposed measures are disproportionate, costs are not understood fully, and the Precautionary Principle is applied inappropriately in scientific assessments, leading to harm being overstated because of the use of worst case or hypothetical analyses. When regulators overstate harms, the resulting benefits of regulatory action are, in consequence, exaggerated.

When used to support the implementation of risk management laws, CEA helps highlight disproportionate regulatory choices, forces a more rigorous understanding of benefits (and the scientific evidence on which they are based), requires costs to be identified fully, makes the use of precaution transparent, and improves the design of implementation measures.

(These issues, and the need to develop mechanisms to improve the quality of implementation decisions at EU-level, have been identified in the *ERF Monograph 'Risk*

Management and the EU's Administrative State: Implementing Law through Science, Regulation, and Guidance' 2019)

EU BETTER REGULATION AND CEA

For over twenty years, EU regulators have applied simple cost effectiveness tools when designing risk management interventions. CEA has been used as a part of the technical decision-making processes when setting Emission Limits for pollutants and Occupational Exposure Limits for the exposure of workers to toxic substances, for example. The purpose of CEA has been 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.

This is, however, an incomplete 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 contrast, robust CEA methods require 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 refined its approach to using CEA. Within the 2017 Better Regulation Toolbox, CEA is included as one of the analytical methods that Commission officials can use to compare options in the ex ante or ex post phase of law-making (Better Regulation Toolkit #57).

Whilst the Commission's recognition of CEA as a decision-support tool is to be welcomed, there are a number of problems:

- The importance of CEA as a mechanism for assessing the benefits and costs of interventions designed to save or improve lives, or to protect the natural world, is not recognised explicitly in Toolkit #57.

- Better Regulation requirements for the assessment and management of risk, set out in Toolkit #15, do not encompass the use of CEA.

- Finally, unlike the situation in the USA, the use of CEA to assess measures designed to reduce human health, public safety, or environmental risks is not recommended. For US regulators, OMB Circular A-4, first issued in 2003, explicitly recommends CEA, alongside other measures, to be used for all regulations that seek to cut safety or health risks.

ERF OBSERVATIONS

CEA, when used well, is one of the most important decision support tools used to inform ex ante and ex post assessments of measures to manage risks. It focuses on the ultimate expected improvements in health or the environment of policy interventions.

Robust CEA 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 of 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. It provides regulators with a baseline 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.

Over the last fifteen 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:

- **Revise the Better Regulation Guidelines to explicitly recommend the use of CEA for all measures designed to manage risks to health; safety, or the environment,** including proposed implementing measures;
- **Recognise within the Better Regulation Guidelines the need to base estimates of the benefits of risk management decisions on the weight-of-evidence,** avoiding over-claiming through

worst case scenarios and other similar precautionary methods;

- **Require the Regulatory Scrutiny Board to verify that the ultimate benefits of all regulatory proposals, designed to manage risks to safety, health, and the environment, are fully identified, credible, measurable, and capable of being assessed on an ex post basis,** creating a formal quality '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 measures, including implementing decisions, designed to protect health, safety, and the environment,** improving the basis for future decision-making and informing the development of risk governance policies; and
- **Promote the creation and publication of compatible datasets from past CEAs carried out at EU-level,** stimulating public scrutiny and methodological refinement and facilitating benchmarking across interventions.

**European Risk Forum
May 2020**

Richard Meads and Lorenzo Allio, the Rapporteur and a Senior Policy Analyst at the European Risk Forum, wrote this Highlights Note. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or its members.