PROPORTIONATE MANAGEMENT OF HARMS – RISK MANAGEMENT OPTION ANALYSIS

HIGHLIGHTS NOTE 14

The use of risk-based decision-making, supported by science, focused on the likelihood of harm, and informed by expert knowledge of usage, has historically helped Europe deliver high standards of protection for man and nature, whilst ensuring that the benefits of innovation continue to be enjoyed.

Risk governance at EU-level is, however, evolving. In some policy domains it has increasingly shifted to focusing on restricting the application of technologies primarily on the basis of hazardous properties with the aim of triggering widespread substitution. As yet, the benefits and costs of using a hazard-based approach to managing harms at EU-level are unknown.

At the same time, new regulatory processes are emerging, based on traditional risk analysis models, which provide the means for making large numbers of high-quality risk-based decisions. One of the most important is Risk Management Option Analysis (RMOA).

RMOA enables regulators to establish regulatory priorities rationally and transparently; to structure scientific assessments rigorously; and, to ensure that risk management decisions are tailored to tackle the risks posed by specific applications. Its widespread use helps improve the proportionality of regulatory outcomes.

Action is needed by the European Union to establish a horizontal policy, supported by guidelines, for the wider and more consistent use of RMOA by the European Commission.

This ERF Highlights Note briefly examines the changing nature of risk governance at EU-level, and highlights some of the weaknesses of using the hazard-based approach for managing harms. It assesses the nature and strengths of RMOA, making use of recent work that describes its application in the OECD area. It concludes with a brief list of suggested reforms.

RISK GOVERNANCE – DIFFERENT APPROACHES

Historic experience and good regulatory practice indicate that the management by governments of potential harms is highly effective when using a robust risk-based approach, focused on employing high quality science and knowledge of usage to identify the likelihood of harm posed by specific applications of technologies. Indeed, when using this approach to protecting citizens and nature, governments assess specific threats and exposures; gather evidence of the likelihood of damage; and implement targeted, proportionate, and predictable measures, so that benefits exceeded costs. This risk-based approach has delivered significant benefits for Europeans.

Despite this, the risk-based approach to managing harms has been criticised. Critics argue that the application-specific approach, combined with the lack of information about many technologies used in the EU, is too slow, exposing citizens to avoidable uncertainties and potential harms. Others argue, from a philosophical perspective, that approaches based on science are little more than the opinions of scientists, and as such should not be seen as 'truth'. There are also concerns about the effectiveness of the risk-based approach when dealing with unknown complex exposures that might emerge from the use of modern technologies.

For some opinion-formers and policy-makers these arguments make a compelling case for adopting a new strategy for managing harms. This new approach should be both quicker and stimulate a means to move away from so-called 'unsafe' technologies to 'safe' ones.

At EU-level, these concerns have triggered a change in risk governance and the adoption, in certain policy domains, of a hazard-based approach. This focuses primarily on the intrinsic properties of technologies, using mandatory bans or public blacklists to encourage substitution whenever scientific evidence is considered to be 'uncertain', 'ambiguous', or 'complex, or certain

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properties are considered 'unsafe' or, increasingly, 'undesirable'.

Work by the ERF has identified number of potential problems with the use of hazard characteristics, combined with the extensive use of the substitution principle, to manage potential harms. Possible problems include:

- **Scientific scepticism** – hazard-based approaches can, in certain circumstances, reject toxicological science in general and the insights of Paracelsus in particular ("the dose makes the poison").

- **Proportionality and evidence-based decision-making** – the EU Treaty imposes consideration of proportionality, and a requirement for decisions to be informed by considerations of benefits and costs is a cornerstone of the EU's Better Regulation strategy. It is unlikely that these requirements can be met when regulatory measures are based primarily on hazard characteristics.

- **Risk-risk tradeoffs** – when applied to real world situations, the operation of hazard-based processes tends to trigger a complex process of substitution, often involving greater use of less well-understood but functional alternatives. This may create a risk-risk tradeoff whereby net risk is not reduced.

- **Loss of economic and social benefits** – hazard-based decision-making takes no account of the likelihood of harm or of the benefits of regulated technologies, including those with hazardous properties. In the light of this, benefits may be lost without any evidence of a reduction in harm.

- **Irreversible damage** – if a product or process is banned because of its hazardous properties then, for the users and owners, this is probably irreversible, even if scientific understanding advances or decisions have been based on poor quality science.

- **Workability** – evidence from the use of the substitution principle in Europe suggests that it may be unworkable when used on a significant scale. 'Safer' alternatives may not always exist, and companies may be unwilling to invest to develop them.

- **Trade frictions** – global trade rules, covering technical barriers to trade and phyto-sanitary requirements, require restrictions to be based on good quality science and the assessment of risk (not hazard only).

- **Legitimacy** – finally, hazard-based decision-making does not provide a clear rationale for government intervention. There is no evidence of benefits, for example, but just the potential costs, because a clear causal link between the application of a technology and the likelihood of harm has not been established. The lack of a clear rationale for the use of the powers of the state undermines accountability and legitimacy.

This evolution in risk governance has taken place without a fully informed debate about the potential costs and benefits of a hazard-based strategy for managing harms.

At the same time, new approaches for improving the quality of risk-based decisions have begun to emerge in the OECD area. These are based on the characteristics of so-called 'classical' Risk Analysis set out in the United States of America in the 1980s. One of the most important approaches is Risk Management Options Analysis (RMOA).[1]

RISK MANAGEMENT OPTIONS ANALYSIS

RMOA is a set of processes that are used by a number of OECD member states to help regulators make high quality decisions when implementing complex risk management laws.

RMOA processes help establish regulatory priorities, often based on risk characterisation that combines hazardous properties with evidence of use or exposure; structure scientific risk assessments of priority technologies; and ensure that risk management decisions are tailored to tackle application-specific risks, thereby limiting unintended negative consequences.

Whilst there is no single model of RMOA used by all OECD members, the overall approach has a number of evident strengths that help improve the quality of regulatory decision-making. These include:

- Use of **well-understood principles and practices of risk analysis** (assessment, management, and communication) articulated clearly in the 1980s, and shared widely amongst OECD members;

- Focus on making **regulatory decisions on the basis of the likelihood of harm**, supported by scientific evidence and application-specific knowledge, rather than hazardous properties alone;

- Focus on the **application-specific assessment and management of risk**, ensuring a tailored approach to the selection of risk management options rather than using a generic approach based on substitution;

- Provision of processes to help **overcome two of the endemic weaknesses of the implementation phase of the policy cycle** – a mismatch between technical or scientific capacity and the scope of laws, and overlapping risk management laws;

[1] RMOA is also known as Regulatory Management Options Analysis in some countries and regulatory agencies.

- Use of rational, predictable, and transparent decision-making processes, thereby strengthening **"process legitimacy"**;

- Embeds, at its best, many **good practices for the implementation of risk analysis by the Administrative State**. These include standards for scientific integrity; stakeholder consultation; assessment of alternatives, benefits, and socio-economic impacts; peer review of scientific assessments; standard risk assessment methodologies; and formal review of all risk management options.

- Emphasis on the **proportionality** of final risk management decisions

The application of RMOA processes at EU-level can provide a means to improve the effective functioning of what we call the 'Administrative State', when it carries out one of its most difficult tasks: the extensive range of decisions needed to manage potential harms posed by the production and use of technologies.

As yet the use of RMOA is inconsistent, reflecting, in part a lack of guidelines. At EU-level, ECHA and a number of EU Member States use RMOA-type processes on a voluntary basis within REACH. Some EU Member States have begun to evolve the application of RMOA to the management of the use of chemicals, including the adoption of good practices for consultation of stakeholders. More work is, however, needed to widen the application of RMOA processes in areas such as the overlap between REACH and OHS legislation.

ERF OBSERVATIONS

The emergence of RMOA is highly relevant for the evolution of the EU's Better Regulation Strategy. Its insights and practices should inform the design of future legislation at EU-level, including laws designed to realise the ambitions of the Green Deal. RMOA's principal application, however, should be in strengthening the effectiveness of the EU Administrative State, when it implements complex risk management laws using regulations, substantive guidance, and standards. (The strengths and weaknesses of the EU's implementing mechanisms are analysed in the *ERF Monograph 'Risk Management and the EU's Administrative State – Implementing Law through Science, Regulation, and Guidance' (2019)*.)

In order to make greater and more effective use of RMOA at EU-level, two groups of changes are needed: reforms to strengthen parts of the governance of the EU Administrative State; and, policies and guidance to embed the 'horizontal' use of RMOA. **Specific improvements could include:**

Law of Administrative Procedures – the EU legislature should develop and adopt a comprehensive Law of Administrative Procedures. This should embed the principles of good administration into law, strengthen judicial review, provide legally enforceable standards and procedural rights and encompass all significant rule-making adjudication processes used by the EU Administrative State.

Proportionality Principle – the Council of the EU Ministers should adopt dedicated Conclusions calling for a more robust and systematic application of the principle.

Commission Communication on Proportionality – the European Commission should define the meaning and usage of the Proportionality Principle, possibly in the form of a Communication. The Communication should be informed by legal requirements set out in the Treaty and in the jurisprudence of the EU Courts. It should explain how the principle should be used to improve the quality of regulatory decision-making, including implementation measures.

Scientific Integrity Policy – the European Commission should develop and adopt, possibly in the form of a Decision, minimum standards for the quality, collection, validation, and use of scientific evidence that all directorates and agencies must respect. These should be based on global best practices.

Risk Analysis Policy – the European Commission should develop and adopt, possibly in the form of a Decision, minimum standards for the assessment, management, and communication of risk. These should reflect best practices for RMOA and should focus on application-specific assessment and management of potential risks, reflecting the likelihood of harms.

Risk Management Options Guidelines – the European Commission should develop, for example in a Communication, 'horizontal' guidelines for the selection of risk management measures when implementing legislation. These should provide transparent processes for managing overlaps and require measures to be application-specific and informed by assessments of alternatives, risk-risk, and socio-economic impacts.

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