EUROPEAN RISK FORUM - POLICY NOTE 06

NEW TECHNOLOGIES - MAXIMISING THE BENEFITS AND MINIMISING THE RISKS

2007

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.

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EXECUTIVE SUMMARY

In modern economies, innovation is the long-term driver of growth. It raises productivity, provides jobs, enhances consumer choice, and creates wealth. In turn, greater wealth enables societies to achieve social and political goals. Over time, the pace and nature of innovation is heavily influenced by the development and diffusion of new "enabling technologies". Modern examples include nanotechnology and information and communication technologies (ICT), as well as emerging applications of biotechnology. Diffusion of new technologies is, however, difficult to achieve. New technologies must, in general, compete with existing, well-understood technologies.

Public risk management policies in general, and the way in which the potential risks posed by new technologies are assessed and managed, play a major role in shaping the framework conditions that influence the rate and extent of diffusion of new general purpose technologies. Over time, public management of risk can affect demand for new technologies and the time, cost, and certainty of investments in innovation.

The approach taken at EU-level to manage the risks posed by new technologies continues to evolve. Technology-specific legislation, combined with a precautionary approach, has limited the use of modern biotechnology. On the other hand, the European Commission has used scientific-based mechanisms to identify emerging risks and to avoid stigmatising mobile phone technology.

More needs to be done to develop a formal EU-level framework for maximising the benefits of new technologies and for minimising risks. Specifically:

- Develop a formal policy for managing risks posed by new technologies. This should require risk management legislation to be technologically-neutral;

- Invest, jointly with industry and global trading partners, in high quality science to understand the specific risk characteristics of new technologies;

- Ensure that additional risk assessment and management requirements for new technologies are science-based and application-specific;

- Implement additional risk assessment and risk management requirements using flexible guidelines;

- Expand the scope of the European Commission's consultation and impact assessment tools to include the development of guidelines;

- Reform 'comitology' rules to increase the openness and accountability of the decision-making process;

- Require all significant new risk assessment and risk management guidelines for new technologies to be subject to ex post evaluation

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1. BACKGROUND

In modern economies, innovation is the long-term driver of growth. It raises productivity, provides jobs, enhances consumer choice, and creates wealth. In turn, greater wealth enables societies to achieve social and political goals, such as enhanced welfare provision, more environmental protection, greater consumer protection, and increased investment in education.

Innovation takes many forms. It includes the creation and introduction of new products, processes, and services in all sectors – manufacturing and services, high-tech and low-tech. It encompasses revolutionary and evolutionary change. It includes intangibles as well as tangibles – investment in R&D and marketing as well as investment in new production equipment.

Over the medium and long-term, the pace and nature of innovation is heavily influenced by the development and diffusion of new "enabling technologies". Sometimes described as "general purpose technologies", these open up new opportunities in a wide range of sectors; have applicability in a wide variety of products and services; and possess considerable scope for improvement and elaboration. Modern examples include nanotechnology and information and communication technologies (ICT), as well as emerging applications of biotechnology.

Research evidence suggests that diffusion of new technologies is difficult to achieve. In modern, mature economies, new technologies must, in general, compete with existing, well-understood technologies. In many cases, moreover, existing technologies enjoy advantages of cost, predictability, and stability. Displacement tends to occur only when new technologies offer significant and substantial advantages. In many sectors, existing technologies remain attractive for long periods of time.

Well-designed public policy plays a major role in helping businesses overcome these problems. Availability of capital, flexibility of markets for labour, products and services, and positive attitudes of citizens towards science, technology, innovation, and risk-taking, for instance, are all influenced by government decisions.

Public risk management policies in general, and the way in which the potential risks posed by new technologies are assessed and managed, also play a major role in shaping the framework conditions that influence the rate and extent of diffusion of new general purpose technologies. Over time, public management of risk can affect the scale of demand for new technologies and the time, cost, and certainty of investments in new products and processes.

2. RISK MANAGEMENT AND NEW TECHNOLOGIES

Managing the potential risks posed by new technologies is a difficult challenge for governments. New technologies, especially those derived from scientific discovery and technical knowledge, may pose hazards to human health, public safety, or the environment. Indeed, a degree of public uncertainty often accompanies the introduction of new technologies. A further problem for policy-makers is that technological change is increasing in speed and in the extent and nature of application, making traditional legislative and organisational structures redundant in some cases.

Major changes are also taking place in the processes used by governments to manage risks. Traditional, technocratic risk management methods, based principally on science and which focus on reducing risk below acceptable levels, are being challenged. Some governments now place more emphasis on consultative decision-making processes, whilst also seeking to meet wider social goals. In other countries, there is more use of precaution and a weakening of the pre-eminent role of science.

Within this context, governments seek, in general, to protect citizens from risk, whilst at the same time retaining public trust, promoting innovation, and facilitating diffusion of new general purpose technologies. Based on evidence from a number of different countries and technologies, it is possible to identify a number of "success factors" that influence the ability of policy-makers to achieve these goals. Specifically:

- Public concerns about the potential negative consequences of new technologies are managed through substantial public investments in science (to identify hazards, risks, exposures, and risk assessment methods) and the use of consultative, transparent and open processes to develop new regulatory requirements.

- Primary risk management laws, developed by elected law-makers, determine the social acceptance of major, generic categories of risk, with case-by-case implementation delegated to technical regulatory decision-making processes[1].

- Regulatory frameworks and processes, used to implement primary risk management laws, are predictable, timely, and transparent, as well as being able to respond flexibly and rapidly to new scientific knowledge.

- High quality and internationally-accepted science, focused on risks, exposures, and specific applications, is used to identify potential threats to human health, public safety, and the environment posed by new technologies.

- Risk assessment and management requirements for new technologies are set out in tailored, mandatory guidelines that are based on science and are developed using modern regulatory management processes (including open consultation and a realistic assessment of the costs and benefits of different options).

[1] In this paper, 'primary' law refer to legislation made by elected parliaments or equivalents: this distinguishes it from regulatory decision-making, whereby officials implement laws on a case-by-case basis.. The equivalent at EU-level is described as "secondary legislation" (most notably EU Directives and Regulations): the EU treaty is the primary-level of law-making. At EU-level, secondary legislation is implemented through a range of mechanisms, including 'comitology' (a process that involves Member State governments), mutual recognition, and technical standards.

3. EU-LEVEL POLICIES

Three examples illustrate the different strategies employed at EU-level since the late 1980s to manage the risks and maximise the benefits of new general purpose technologies.

Unlike many other parts of the OECD, the EU has taken a technology-specific approach to regulating the use of **modern biotechnology**: one of the most important modern general purpose technologies. EU rules assume that the use of modern biotechnology within processes, or to produce new products, poses intrinsic and specific risks. As a result, the EU has passed a number of technology-specific measures including biotech-specific controls over contained use, deliberate release, and labelling. In many cases, these controls are additional to other, existing risk management rules. The EU's approach is not, in general, supported by scientific evidence but has been justified as a means of responding to high levels of public concern and hence creating consumer confidence.

Alongside this approach, the EU has also, used application-specific guidelines to take a flexible approach to control the use of biotech, within existing, technology-neutral risk management laws. In human pharmaceuticals, for example, EMEA has developed science-based guidelines for the risk assessment of bio-similars (generic versions of biotech-based drugs).

As a contrast, the health risks posed by **information and communication technologies (ICT)** have been managed at EU-level using a different approach. In general, the EU has used a more science-based, technology-neutral approach that has made extensive use of existing primary risk management rules, such as directives covering telecommunications and electrical equipment, worker safety, and general consumer product safety. Within this framework, new, application-specific safety standards have been adopted and applied to new products using the so-called "new approach" to managing product safety risks. For instance, safety levels with respect to human exposure to radio frequency and electro-magnetic fields (EMFs) have been developed on the basis of internationally-accepted science, despite public concern about potential health hazards. At the same time, fears about the impact of exposure to EMFs have been managed through investment in scientific research and periodic reviews of evidence by independent scientists.

Environmental risks posed by ICT have been managed differently. Technology-specific legislation, most notably electronic waste (WEEE) and hazardous substances in electrical equipment (RoHS) rules, has been put in place.

The EU's embryonic approach to regulating the use of **nanotechnology** provides a third example. So far, the European Commission has followed a science-led strategy. For instance, advice from the EU's independent scientific committee responsible for emerging health risks (SCENHIR) suggests that although more needs to be done to characterise fully the potential effects of nanotechnology and to develop appropriate risk assessment methodologies, there is, as yet, no formal scientific recommendation to develop new, technology-specific legislation. Additional risk assessment or risk management requirements are to be developed using application-specific guidelines and existing risk management rules.

There is, however, an emerging debate, involving Member States, the European Parliament and opinion-formers, as to whether or not technology-specific legislation is also required, on precautionary grounds, because of the uncertainties surrounding the impact of nanotechnology and the potential scale of its future use.

4. RECOMMENDATIONS

The approach taken at EU-level to manage the risks posed by new technologies, whilst also facilitating innovation and technology diffusion, continues to evolve. Technology-specific legislation combined with a precautionary approach has been used in the past. In the case of modern biotechnology, it is argued, this has created stigmatisation and other economic obstacles to technology diffusion, leading to substantial economic and social losses without any measurable improvement in environmental or health protection. On the other hand, the European Commission has also used scientific-based mechanisms to identify emerging risks and has employed a risk-based approach to avoid stigmatising mobile phone technology.

Although the recent actions by the Commission are to be welcomed, more needs to be done to develop a formal framework for maximising the benefits of new technologies and for minimising risks. Possible policy and regulatory improvements include:

- **Develop a formal policy for managing risks posed by new technologies. This should require risk management legislation to be technologically-neutral** and should recognise the negative consequences for citizens of stigmatising new ideas, and locking-in old technologies;

- **Invest, jointly with industry and global trading partners, in high quality science to understand the specific risk characteristics of new technologies and to develop relevant risk assessment tools and methods.** Widespread consultation should be used to ensure that such programmes are informed by public concerns based on evidence;

- **Ensure that additional risk assessment and management requirements for new technologies are application-specific,** derived from high quality scientific evidence, and based on a realistic understanding of risk and exposure;

- **Implement additional risk assessment and risk management requirements using flexible guidelines** that permit rapid, science-based response to technical progress and are consistent with wider international norms;

- **Expand the scope of the European Commission's existing regulatory process management tools (most notably consultation and impact assessment) to include the development of guidelines** defining additional risk assessment and risk management requirements for new technologies;

- **Reform 'comitology' rules to increase the openness and accountability of the decision-making process** and to require EU regulatory committees to provide additional, substantive evidence, if the advice of scientific advisers is not accepted;

- **Require all significant new risk assessment and risk management guidelines for new technologies to be subject to ex post evaluation** of effectiveness, scientific progress, and unintended consequences, including 'risk-risk' costs and impacts on technology dissemination.

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.

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