



## **EUROPEAN RISK FORUM – POLICY NOTE 23**

### **INNOVATION AND THE REGULATION OF RISK**

**July 2013**

## 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 practitioners 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.

## **1. INNOVATION AND THE BUSINESS ENVIRONMENT**

Innovation is the single most important driver of economic growth. It flourishes when societies create conditions in which investors, managers, and entrepreneurs are encouraged to take risks. Innovation encompasses the creation of new products and services and the use of new processes and operating methods. It includes revolutionary changes as well as changes resulting from continuous improvement. It is important for companies of all types in all sectors. Companies and private sector investors play the leading role, and large-scale enterprises are disproportionately important because of their investments in R&D.

Governments have a major role to play in creating a business environment that is supportive of innovation. A stable and supportive macro-economic environment is important, and this is heavily influenced by fiscal and monetary policies. Alongside this, positive “Enabling Conditions” are critical, and governments have a role to play. These conditions include positive attitudes towards risk, enterprise, science, and new technologies; favourable market conditions (level and nature of demand, and ‘access’ to markets); broad development and widespread dissemination of new knowledge and ideas; ready availability of well-qualified people; and easy access to capital.

Regulation of risk affects three important aspects of the business environment: attitudes to risk acceptance, science, and new technologies; market conditions, including regulatory-induced barriers to market access; and, access to knowledge and ideas.

## **2. INNOVATION AND RISK MANAGEMENT**

### **2.1. ATTITUDES**

Public attitudes influence risk-taking, regulatory frameworks, the acceptance of new products, market opportunities, and the development of new operating processes.

Governments, through well-designed policies and processes, can help build confidence in the value of new technologies and the importance of accepting risks. An example is the evidence-based approach taken by the EU to manage social concerns about the perceived hazards posed by EMFs, thus supporting innovation in mobile devices.

Equally, public policy can exacerbate risk aversion and create barriers to the dissemination of new technologies or to continued investment in existing products. Technology-specific rules, for example, stigmatise new ideas, suggesting they are less safe or desirable, as well as increasing the time and cost of product development. At EU-level, such an approach has crippled investment in non-medical biotechnology and triggered de-localisation of R&D assets. Calls for similar ‘horizontal’ rules may, if implemented, limit investment by EU-based enterprises in nanotechnology: one of the “platform technologies” of the future.

Problems also occur if governments make risk management decisions that place disproportionate emphasis on social concern, hazard, and precaution rather than evidence, science, and risk. Such decisions send clear messages to investors and managers about European attitudes to technologies and influence future investment decisions. The recent decision by the EU to ban the use of neonicotinoids, along with the proposed regulatory framework for endocrine disrupters, suggest a shift towards

values that question the scientific method and favour, in its place, systematic risk aversion. Inappropriate and disproportionate use of the EU's Precautionary Principle reinforces these concerns. When attitudes change, businesses revise capital allocation, investment, and innovation decisions.

## **2.2. MARKETS**

Demand factors, including market access, along with product development economics, play a critical role in influencing the scale, pace, and nature of innovation. Regulation of risk can, and does, influence these factors.

High quality, science-based rules, supported by predictable regulatory processes help build consumer confidence in the safety and quality of new technology-based products and provide a “gold standard” for overseas markets, as is the case with the regulatory framework for Medical Devices in the EU.

Poor quality regulations and decision-making processes raise the time and cost of product development projects, especially in high tech sectors, whilst at the same time creating uncertainty. Taken together, these factors increase the capitalised cost of innovation investments, expanding the scale of the market opportunity needed to recover the cost of capital. When this occurs, innovation investments are distorted and, in many cases, reduced. Rationalisation of innovation assets and retention of older technologies also takes place. EU regulation of risk has triggered such decisions in a range of sectors, including veterinary medicine, novel foods, crop protection, green biotechnology, and productivity-enhancing animal health products.

Regulatory-based factors can also reduce the size of markets. Traditionally, this has occurred through direct restrictions on the use of certain technologies or materials, because of fears of potential damage to human health or the environment. Sometimes this has been justified by evidence, such as banning lead additives in petrol: on other occasions, such as restrictions on hormones in beef cattle, decisions have been based on other, non-scientific factors.

Increasingly, market size reductions also occur as a result of stigmatisation, where regulators, through the use of hazard-based ‘blacklists’, and opinion-formers, through media and activist campaigns, amplify social concerns, triggering changes in user behaviour. Market demand is reduced, without scientific evidence of likelihood of harm and without legal due process. A range of sectors, including artificial sweeteners, air fresheners, polycarbonates, and metal coatings, have already experienced this, and more will be exposed to it as the implementation of REACH moves into its latter stages. Loss of existing markets reduces the financial resources for innovation and limits investment in well-established technologies.

## **2.3. IDEAS**

Regulation of risk can also affect the creation and diffusion of ideas. Many policy-makers focus primarily on R&D and new information, when considering the dissemination of knowledge. Companies, in contrast, frequently rely on access to a ‘palate’ of proven technologies, many of which are embedded in substances purchased from suppliers. This is particularly the case for SMEs operating in the downstream parts of the EU's value chains.

Risk management decisions can affect the availability and attractiveness of these well-established technologies, limiting the diffusion of ideas and innovation. A key

issue facing risk managers in most OECD countries is how to develop high quality risk management frameworks for the myriad uses of very large numbers of substances in heterogeneous applications. To date, the EU has struggled to achieve this. In too many instances, over-precautionary and hazard-based legal frameworks, implemented by politicised, poor quality regulatory decision-making processes, have created major threats to the continued availability of proven technologies in a wide range of sectors. In some cases, categories of products or specific applications have been restricted without conclusive scientific proof of harm, as occurred with food ingredients, polycarbonates, phthalates, and brominated flame retardants: in other instances, the disproportionate cost of demonstrating safety or quality or efficacy has triggered voluntary withdrawal of substances, most notably in biocides, crop protection, and animal health.

Taken together, this distorts innovatory activity and inhibits the development of new products and operating processes, especially incremental innovations by smaller companies operating close to end users.

### **3. REFORM**

These problems are not new. Poor quality, hazard-based risk management decisions, that pay more regard to social concern than to science and evidence, have been taking place for over two decades at EU-level. Long-run evidence of this type suggests that attitudes to technology and science have changed, weakening the attractiveness of the EU as a location for certain types of innovation. A particular problem when other, non-EU markets are growing more rapidly than traditional ones. This has begun to influence the investment, innovation, and capital allocation decisions of businesses in a range of sectors.

Over the same time period, significant improvements have been made in the way in which the EU makes legislative and regulatory decisions. Action is needed by EU-level policy-makers to build on its world-leading regulatory processes and to establish a policy and regulatory framework for the management of risk that stimulates innovation whilst using science and evidence to protect citizens and the environment. Possible reforms include:

- Establish a formal EU policy for managing new technologies on a “technology-neutral” basis;
- Ensure that the focus of “Innovation Union” (the Commission’s strategy for stimulating innovation) includes a review of technical regulatory decision-making processes, as well as primary laws;
- Revise the Commission’s IA guidelines to consider the impact of new risk management laws on innovation and to develop guidelines for understanding complex costs and benefits, including product development economics and stigmatisation;
- Develop regulatory process management standards for the use of science in decision-making; and,
- Ensure that ex post evaluations of EU-level risk management rules and their implementation are undertaken rigorously, including completing a review of all controversial decisions taken over the last two decades.

**This background note 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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