RISK REGULATION AND INNOVATION

HIGHLIGHTS NOTE 07

Social choices about the way in which potential risks are managed by governments affect incentives to innovate. This occurs in three important areas:

- public attitudes to risk-taking, science, and technology;
- market conditions, including regulatory barriers to retaining existing products and to bringing new ones to market; and
- access to knowledge and idea.

This ERF Highlights Note briefly addresses these areas and highlights the need for regulators to understand the interface between risk regulation and innovation.

ATTITUDE TO RISK, SCIENCE AND TECHNOLOGY

Public attitudes influence risk-taking, regulatory frameworks, new product markets, market opportunities, technology choices and the development of new operating processes.

Governments, through well-designed policies and processes, can help build public confidence in the value of new technologies and in 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 electro-magnetic fields (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. This may occur through a number of mechanisms, including:

- **Stigmatisation through technology-specific regulation** – Technology-specific rules tend to stigmatise new ideas, **suggesting they are less safe or desirable than existing technologies, as well as increasing the time and cost of product development**. At EU-level, such an approach has for instance crippled investment in 'green' biotechnology and triggered de-localisation of R&D assets. Calls for similar 'horizontal' rules could, if implemented, limit investment by EU-based enterprises in nanotechnology, one of the "platform technologies" of the future. One further consequence of stigmatisation is that **old technologies are preferred to new ones, limiting productivity growth, and slowing down the introduction of new goods and services**.

- **Poorly designed risk management** – Problems also occur if governments make risk management decisions that place **disproportionate emphasis on risk avoidance, social concern and hazard rather than on evidence, science, and the acceptance of risk**. An example here is the recent decision by the EU to ban the use of neonicotinoid seed treatment. It was taken without internationally accepted, reproducible, and validated scientific evidence. A further example is a proposed hazard-based regulatory framework for endocrine disrupters supported by controversial science. This type of regulatory decision suggests a shift towards post-modern values. These appear to question the relevance of traditional "scientific evidence" (most notably scientific risk assessment and the reliance on established toxicological models) as a basis for regulating potential risks. Post-modern values favour, in its place, systemic short-term risk aversion. Inappropriate and disproportionate use of the EU's Precautionary Principle, as well as hazard-based approaches to regulation.

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When public attitudes change, businesses revise locational, capital allocation, investment, technology, and innovation decisions.

MARKET CONDITIONS

Demand factors, including market access, along with product development economics, play a critical role in influencing innovation. Regulation of risk influences these factors. **Well-designed risk management rules can help to shape market conditions favourably:**

- **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 can provide a "gold standard" for overseas markets, as is the case with the regulatory framework for Medical Devices in the EU. Such processes facilitate market access outside the EU, creating a form of intangible asset for successful manufacturers and building business value.

- **Quality and safety standards, if based on science, risk and expert processes,** facilitate market access. They also allow for a flexible and proportionate response to new knowledge. The EU's "New Approach" to regulating consumer safety has achieved this.

In contrast, poor quality regulations and decision-making processes increase the time and cost of product development projects, especially in high tech sectors, whilst at the same time creating uncertainty and confusion. Taken together, these factors increase the capitalised cost of investment in innovation, expand the scale of the market opportunity needed to recover the costs of investment and threaten the value of businesses. When this occurs, innovation investments are distorted and reduced. **Rationalisation of innovation assets and retention of older technologies also occurs.** EU regulation of risk has triggered such decisions in a range of sectors, including veterinary medicine, novel foods, crop protection, and green biotechnology.

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. However, on too many occasions, such as restrictions on Bisphenol A, decisions have been based on non-scientific factors.

Increasingly, market size reductions also occur **as a result of regulatory-driven stigmatisation**, where regulators use hazard-based regulations to generate so-called public "blacklists". In turn, some opinion-formers, through media and activist campaigns, use such statements of public disapproval to amplify social concerns, triggering changes in user behaviour. As a result, market demand is reduced, without scientific evidence of a causal link to harm and in the absence of legal due process. A range of sectors, including artificial sweeteners, air fresheners, polycarbonates, and metal coatings, have already experienced this form of market dynamic, and more will be exposed to it as the implementation of REACH progresses.

Loss of existing markets reduces financial resources for innovation and limits investment in previously well-accepted areas of technology.

ACCESS TO KNOWLEDGE AND IDEAS

Regulation of risk can also affect the creation and diffusion of ideas. This occurs through two processes:

- **Loss of access to established technologies because of regulatory-induced decisions** – In many sectors, companies 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 well-established technologies, limiting the diffusion of ideas and innovation. If the mandatory costs of ensuring that existing substances and their uses meet new standards of safety (or quality or efficacy) exceed the capitalised future margin of a substance then, in general, they will be voluntarily de-listed. Downstream users will lose access to them, along with all of their embedded technologies.

Indeed, 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 throughout complex value chains. To date, the EU has struggled to achieve this, and in too many instances, decisions have been of poor quality. This has created major threats to the continued availability of proven technologies. Categories of products or specific applications have been restricted without conclusive scientific evidence of harm, as has occurred with food ingredients, polycarbonates, metallic chemicals, phthalates, and brominated flame retardants: in other instances, the disproportionate cost of demonstrating safety or quality or efficacy of well-established materials has triggered voluntary withdrawal of substances, most notably in biocides, crop protection, and animal health.

Taken together, this loss of existing substances (and the knowledge embedded within them) distorts innovatory activity and inhibits the development of new products and operating processes, especially incremental innovations by smaller companies operating close to end users.

- **Diversion of resources away from new ideas because of the cost of "Defensive R&D"** – Loss of existing ideas is not the only problem triggered by the growth of Defensive R&D requirements in the EU.

Mandatory expenditures to demonstrate the safety or efficacy or quality of existing substances, even when there is no evidence of harms, diverts scarce resources away from investment in new ideas. Companies when faced by this requirement do not, in general, allocate additional resources to innovation. In the light of this, innovation resources in the EU are used, all too frequently, to "prop up" old technologies rather than to develop new ones or to support incremental improvements.

Emerging evidence from the initial evaluation of the EU's REACH programme for the management of risks posed by chemical usage highlights the problem. Other sectors have experienced similar problems, most notably animal health, biocides, and crop protection.

When societies choose to manage risks by diverting resources away from investment in new ideas, then such decisions should be taken cautiously and with a full understanding of the potential costs and benefits. Evidence of potential harms to be alleviated should be based on high quality scientific evidence and a credible assessment of risk. Too often, however, this has not occurred at EU-level.

ERF OBSERVATIONS

For Europe's citizens, jobs, wealth, and their quality of life depend upon innovation – the main 'engine' of economic growth. It is the result of risk-taking by managers and entrepreneurs. 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 the scale 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 an impact. These conditions include positive attitudes towards risk-taking, enterprise, science, and new technologies; favourable market conditions (including the 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 access to appropriate forms of risk capital.

A wide range of government policies affects the enabling conditions for innovation. Amongst them is the regulation of risk – i.e. the way in which societies expect governments to protect them from actual or potential threats.

Well-informed public policy recognises these impacts and sets out to *create an appropriate balance between managing risks and supporting innovation*. Evidence from OECD countries suggests that the best way to achieve this balance is to ensure that decisions about managing risks are based on evidence – *principally high quality science, informed by a rigorous understanding of benefits and costs, and undertaken using processes that meet global standards of good administration*. A proper understanding of possible costs should include an explicit assessment of the potential impacts of any proposed measure on innovation.

Decision-making based on scientific evidence is essential if risks are to be managed effectively without eroding investment in innovation. High quality science provides unique insights into potential risks, supports the development of credible risk assessment (based on real-world exposures), and enhances the predictability of regulatory outcomes. Used well, it helps to create a more favourable environment for investment, building business confidence in the capacity of governments to make high quality decisions.

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Richard Meads, the European Risk Forum's Rapporteur, 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.