The ERF Study

European Risk Forum
Monograph

Fostering Innovation
Better Management of Risk

Executive Summary

Innovation and Risk Management

Innovation is the single most important driver of growth in a mature economy. It flourishes when societies create conditions in which investors, managers, and entrepreneurs are encouraged to take risks and hence create new sources of wealth and work.

Shaping a business environment that meets these requirements so that innovation and risk-taking are stimulated is an issue of critical importance for the EU. After a period of technological catch-up in the decades after the Second World War, growth in productivity in the EU has lagged that in the USA and Japan since 1995. Innovation, its economic motor, has slowed down. Compared to its global peers the EU has fallen behind, leading to slower economic growth, less employment, and lower living standards.

One cause of this is a regulatory environment at EU-level that has become increasingly characterised by risk avoidance rather than risk acceptance and a preference for social concern rather than science when making risk management decisions. Regulatory processes used by the EU to manage risks reflect these factors, creating further barriers to innovation.

Social choices about the way in which potential risks are managed by governments affect three important aspects of the business environment: 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 ideas. Over time, this affects incentives to innovate.

The Innovation Principle

One way of restoring confidence and incentives to innovate, whilst ensuring a high standard of protection for citizens and the environment, is for the EU's institutions to adopt the "Innovation Principle".

A simple, straightforward idea, **the Innovation Principle requires that whenever the EU's institutions consider policy or regulatory proposals, the impact on innovation should be fully assessed and addressed.**

If adopted and used well, the principle will raise awareness of the link between regulation and innovation; it will signal to global investors the commitment of the EU to promote innovation, improving business confidence; it will align regulatory policy with other

economic goals, enhancing coherence; and it will ensure greater balance in regulatory decision-making, helping decision-makers become more aware of the trade-offs needed to protect citizens and the environment from risks whilst also supporting innovation. Over time, its application by the EU's regulators will rebuild confidence and help to strengthen incentives to invest in innovation in the EU.

To be effective in informing the EU's decision-making processes, the Innovation Principle must be embedded, at all levels of government, in a framework of policies, guidelines and institutional structures. Requirements to make extensive use of high quality scientific advice must form part of this framework.

Recommendations

Whilst there are clearly problems with the way in which the EU increasingly regulates risks, there are some grounds for optimism as well. Regulatory process management standards at EU-level, most notably impact assessment, ex post evaluation, and stakeholder consultation, meet, and in some cases, exceed global best practice standards. Some of the EU's economic policies have begun to recognise that the regulatory framework is important for innovation.

Urgent action is needed to reinforce and build on these initiatives and to find ways to ensure that innovation is considered fully whenever the EU's institutions consider policy, legislative, or regulatory measures. At the same time, reforms should ensure that the best available scientific evidence is used as the basis to regulate potential risks, protecting citizens and the environment while, at the same time, sustaining and strengthening incentives to innovate.

Ideas for improvement include:

For the three European Union institutions to:

- Issue political statements stressing the importance of ensuring the proper consideration of productivity, innovation and wider impacts, such as jobs, growth, and competitiveness, in the legislative and regulatory decision-making process; and,
- Create a common cross-institutional working group, drawn from all three EU institutions, focusing on the promotion of innovation at EU-level and recognising the joint responsibility for supporting better regulation, risk-taking, and innovation, while protecting human health and the environment at the same time;

For the European Commission to:

- Revise the scope of the portfolios of the Commission Vice Presidents, such that one of them has overall responsibility for co-ordinating all policies designed to promote innovation (a "Vice-President for Innovation");
- Expand the scope of the portfolio of Vice-President Timmermans to require the wider impacts of regulation to be understood and managed, including the impact of risk management regulation on innovation;
- Create an institutional structure close to the centre of government with responsibility for ensuring adherence by all Commission Services and agencies with the new Regulatory and Risk Governance Policies;
- Establish institutional structures close to the centre of decision-making with responsibility for assuring the quality of scientific advice used, throughout the Commission, to inform risk management decisions;
- Revise the mandate of the Impact Assessment Board to ensure greater focus on the linkages between Better Regulation, innovation, and Europe 2020;
- Issue a formal Commission Communication establishing and defining the Innovation Principle as one of the main factors to be considered whenever the EU institutions consider policy, legislative or regulatory interventions. The Commission should also set out the procedural and analytical arrangements necessary for the implementation of the Innovation Principle;
- Revise its Smart Regulation Communication and require officials to consider fully the wider impacts of legislative and regulatory interventions, including links between regulatory frameworks, regulatory processes and innovation;
- Establish a formal science-based regulatory policy framework, in the form of a Commission Communication, to support innovation that bases risk assessment and management on high quality scientific evidence; that balances precaution and proportionality; that includes all relevant expertise; and, that uses transparent information and evaluation processes;
- Establish a formal, 'horizontal' risk governance policy, encompassing good regulatory practices in relation to objectives, risk-taking, science, innovation, countervailing risks, precaution, risk management measures, and good administration. Risk governance principles, along with appropriate guidance notes, should be issued as a Commission Communication;
- Establish a revised policy for the use of scientific evidence when making risk management decisions. This should be based on scientific evidence that is obtained using internationally respected and validated scientific methods, taking into consideration both 'bias' and 'conflicts of interest'; that uses excellence as

the main criteria for selecting and using scientific evidence; and that provides a comprehensive set of key concepts and definition. These requirements should be set out in a Commission Communication;

- Develop a formal policy for managing potential risks posed by new technologies. This should require risk management legislation to be technologically neutral; and,
- Implement changes in the guidelines used to support Impact Assessment, Ex Post Evaluation, and REFIT processes such that officials focus more rigorously on the impacts of risk management measures on innovation.

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1. Introduction

1.1 Innovation, Risk and Science

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[1].

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 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.

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

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

[1] Some SMEs are also important investors in innovation, most notably "gazelles" (fast growth companies and future large-scale enterprises), and technology development companies in high-tech industries, many of which are funded by venture capital.

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.

1.2 EU Policy Framework for Innovation, Risk and Science - ERF Concerns

At EU-level, relationships between innovation, risk, and science are addressed using a complex political and policy framework. Regulatory policy is shaped through the Smart Regulation framework put in place in 2010[2]. Whilst this has strengthened the focus of officials on evidence, impact assessment, and ex post evaluation, the Smart Regulation policy lacks an explicit focus on the relationship between innovation and regulation or on the role of science in decision-making.

Scientific advice is provided to the EU's institutions through a multiplicity of sources but 'horizontal' policies to assure excellence and quality are inadequate and institutional oversight has been eroded by the decision not to continue with the post of Chief Scientific Advisor.

Economic policies have flaws as well. All accept the importance of innovation for the future prosperity of the EU, yet there is little recognition of the impact that regulation can have on innovation. Even when this is highlighted, policy-makers tend to focus on protection of intellectual property, the creation of standards, and reductions in administrative burden for SMEs. The impact of the regulation of risk on innovation is, all too often, overlooked.

Political statements and institutional arrangements exacerbate these weaknesses in the EU's policy framework. Recent actions and statements by the EU's institutions suggest that the political commitment to evidence-based decision-making is weakening. Moreover, political accountability for promotion of innovation is splintered across a number of European Commissioners, making it difficult to ensure that policy is coherent and, moreover, that it takes account of all of the obstacles to innovation, including the way in which the EU

[2] European Commission 'Communication on Smart Regulation in the European Union' (COM (2010) 543)

regulates risks. Finally, the portfolio of the Commissioner responsible for Better Regulation makes no mention of the importance of understanding the wide impacts of regulation, most notably the impact of risk management on innovation.

Work by the European Risk Forum (ERF) suggests that these weaknesses in the EU's policy and institutional framework and their consequences for innovation are not new. Poor quality risk management decisions, that pay more regard to perceived hazards, emotion, and social concern than to evidence and science, have been taking place for over two decades at EU-level. A track record has now been established, suggesting to companies and investors that attitudes to science, technology, and risk-taking have changed. As a result, the EU has become less attractive as a location for certain types of innovation and the allocation of capital has been distorted away from the EU and into other faster growing or better regulated markets. There is, however, little evidence to suggest that the EU's citizens enjoy a higher level of protection from risks than citizens in similar societies.

Without reform, things are likely to get worse. EU decision-makers continue to pursue ever more ambitious risk management goals; to focus on ever more complex activities, including all uses of materials in all of the EU's manufacturing value chains; and to employ untested risk management mechanisms, such as hazard-based decision-making, substitution, blacklists, and stigmatisation, designed to promote wider regulatory impacts. Moreover, all of this appears to have been undertaken without any substantive awareness, amongst decision-makers, of the potential negative impact of excessive or unnecessary risk management decisions on innovation or of the inconsistent quality of evidence used to inform complex regulatory decisions.

Although there have been significant improvements in the way in which the EU makes legislative and regulatory decisions over the last two decades, further action is needed to restore incentives to innovate whilst at the same time protecting citizens and the environment. To achieve this, a number of major reform priorities have been identified by the ERF[3]. They include:

- A law of administrative procedure to ensure that all actions by the EU institutions to implement laws meet accepted standards of good administration;
- A new policy and institutional framework to assure the quality and excellence of scientific evidence used to inform decision-making; and,
- A new decision-making principle to inform all policy and legislative decisions – The Innovation Principle.

[3] See European Risk Forum 'The ERF Action Plan for Improved Risk Management in the EU' (2012)

1.3 The Innovation Principle

The Innovation Principle encompasses a simple and straightforward idea. It requires the EU's institutions, whenever they consider policy or regulatory proposals, to fully assess and address the impact on innovation.

If adopted and used well, the principle will raise awareness of the link between regulation and innovation; it will signal to global investors the commitment of the EU to promote innovation, improving business confidence; it will align regulatory policy with other, economic goals, enhancing coherence; and it will ensure greater balance in regulatory decision-making, helping decision-makers become more aware of the trade-offs needed to protect citizens from risks whilst also supporting innovation. Over time, its application by the EU's regulators will help to strengthen incentives to invest in innovation in the EU.

With the support of companies responsible for investing over Euro 30 billion annually in innovation and employing more than 1.5 million people globally, the ERF has, since 2013, promoted the adoption by the European Union of the Innovation Principle. Two letters, signed by CEOs, have been sent to the leaders of the EU's institutions.

1.4 Coverage[4]

This monograph examines ways in which the Innovation Principle could be embedded into the EU's decision-making processes for making risk management decisions. It focuses on finding ways to achieve this within an approach to managing risks based on high quality scientific evidence.

The initial part of the document considers the links between innovation and the management of risk (section 2). It explains how governments can help to create an environment for business that encourages innovation. It shows how risk management regulation affects the business environment, highlighting positive and negative impacts. The extent to which the EU's policy frameworks recognise links between innovation and regulation of risk is also assessed. In the next section of the monograph, the EU's governance of risk is analysed (section 3). It considers the nature of the EU's approach, examining the extent to which risk governance takes account of the impact of management of risks on innovation.

[4] This monograph, its findings, conclusions, and recommendations, focuses solely on the relationship between the management of risks ("risk regulation") and innovation by the private sector; the primary motor of future productivity growth. In doing so, it comments on parts of the Better Regulation agenda, most notably science-based decision-making, ex ante impact assessment, and ex post evaluation. Other Better Regulation issues, such as transparency, access to documents, consultation, laws to govern administrative procedures, regulatory design, and regulatory convergence, are not considered. Many of these issues are, however, addressed in other ERF publications.

A concluding section proposes areas of improvement in the EU's institutional architecture, policies, and guidelines (section 4). The final section sets out a series of recommendations that, if implemented fully, would pave the way for embedding the Innovation Principle into the EU's regulatory decision-making processes (section 5).

Two appendices are also included: one sets out suggested improvements in the Commission's IA guidelines, whilst the other lays out general principle for officials to consider when examining the possible impact of risk management measures on innovation.

2. Innovation and the Management of Risk

2.1 Innovation and Government

Innovation is the single most important driver of growth in a mature economy. It flourishes when societies create conditions in which investors, managers, and entrepreneurs are encouraged to take risks and hence create new sources of wealth and work.

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 incremental change. It includes intangibles as well as tangibles – investment in R&D and marketing along with spending on new production equipment, operating methods, and ways of organising work.

Decisions by companies and private investors determine the level and nature of innovation in any developed, open economy. Large-scale enterprises are disproportionately important because of the scale of their expenditure on R&D, and because of their role in stimulating innovative activity in suppliers[5].

A number of factors influence the ability of companies to innovate. Governments and public institutions affect most of them. Through their actions, governments play a major part in constructing an environment that can encourage innovation by companies. 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.

[5] In the USA, multi-national companies employ 19% of workers, account for nearly 75% of business R&D, and deliver over 40% of gains in labour productivity. Evidence from The European Roundtable of Industrialists suggests that a similar picture exists in the EU. See, McKinsey Global Institute 'Growth and Competitiveness in the United States: The role of multi-national companies' (2010) and The European Roundtable of Industrialists 'The Contribution of ERT Member Companies to Growth and Jobs in the EU' (2007)

Enabling conditions form part of the external business environment and provide incentives and critical resources for companies and entrepreneurs to help stimulate innovation and risk-taking. The most important are:

- **Positive attitudes towards risk, enterprise and new technologies** – culture and attitudes influence the willingness of managers and entrepreneurs to take risks, the level of demand for new products and services, technology choices, government policies, and regulatory frameworks;
- **Favourable market conditions** – the incentives and opportunities available to companies and entrepreneurs in markets, along with the obstacles they face in bringing new products to market and retaining the use of existing ones, are the most important drivers of innovation;
- **Broad development and widespread dissemination of new knowledge and ideas** – innovation depends upon the creation, diffusion and availability of knowledge, some of this is the result of new ideas and in other cases it comes from new ways of exploiting existing ideas[6];
- **Ready availability of well-qualified people** – the availability of sufficient numbers of educated and skilled people who are capable of generating new ideas, using new technologies, and adapting to change is a critical input to the innovation process; and,
- **Access to risk capital** – for companies and entrepreneurs, innovation involves two major financial decisions: an investment decision that assesses costs and benefits, and a financing decision based on obtaining the capital that best matches assets, cash flows, and risks

Shaping a business environment that meets these requirements so that innovation and risk-taking are stimulated is an issue of critical importance for the EU. After a period of technological catch-up in the decades after the Second World War, growth in productivity in the EU has lagged that in the USA and Japan since 1995[7]. Today the EU invests less of its wealth in innovation, and is slower to adopt new technologies[8]. Innovation, its economic motor, has slowed down. Compared to its global peers the EU has fallen behind, leading to slower economic growth, less employment, and lower living standards.

[6] Development and dissemination of knowledge and ideas depends on a wide range of factors, including the scale and nature of expenditure on R&D and good interaction between the private sector and the science base (universities and research institutes and other parts of national innovation systems). Regulatory factors are important too.

[7] See for example, Bergeaud A., Cotte G., Lecat R. 'Productivity Trends from 1890 to 2012 in Advanced Countries' (Banque de France, Document de Travail No. 275, 2014)

[8] European Commission 'EU Innovation Scorecard 2014' (2014)

One cause of this is a regulatory environment that has become increasingly characterised by risk avoidance rather than risk acceptance and a preference for social concern rather than science when making risk management decisions. Regulatory processes used by the EU to manage potential risks reflect these factors, creating further barriers to innovation[9].

The extent and nature of this problem can be illustrated by considering the likely impact of today's risk regulation framework at EU-level on historic, current, and emerging technologies. The EU's current risk-averse approach to managing potential risks would have prevented the emergence of steam locomotives, microwave ovens, mobile phone, and x-ray machines. It currently threatens the development of nanotechnology, green biotechnology, components of medical devices, food additives, domestic appliances involving heat (such as toasters), and fire hazard protection in domestic appliances, such as televisions. Looking to the future, the EU's approach to the regulation of potential risks could threaten or prevent a range of innovations including synthetic biology, advanced seed breeding, food production for arid climates, and driverless planes and aircraft.

2.2 Risk Management and Impacts on Innovation in the EU

Public risk management is one of the core functions of modern governments. It helps promote enterprise, protect workers against the potential negative impacts of industrialisation, and protect public safety, human health and the environment from potential risks posed by technologies or lifestyle choices.

Social choices about the way in which potential risks are managed by governments affect incentives to innovate. This occurs because the regulation of risk influences the enabling conditions for innovation, which form part of the business environment, 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 ideas.

[9] OECD, UK Government, and US National Bureau of Economic Research studies support this, showing how regulation inhibits growth in productivity. See for example, Cette G. Lopez J. Mairesse J. "Product and Labor Market Regulations, Production Prices. Wages and Productivity' (NBER Working Paper 20563, 2014); UK Government Office for Science 'Innovation: Managing Risk, Not Avoiding It' (2014)

2.2.1 Attitudes 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. Technology-specific rules, for example, 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 crippled investment in 'green' biotechnology and triggered de-localisation of R&D assets[10]. 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 is that old technologies are preferred to new ones, limiting productivity growth, and slowing down the introduction of new goods and services.

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. Such decisions send clear messages to investors and managers about European attitudes to technologies. In turn, this influences the allocation of capital and, hence, future investment decisions.

As an example, the recent decisions by the EU to ban the use of neonicotinoid seed treatment without internationally accepted, reproducible, and validated scientific evidence, along with a proposed hazard-based regulatory framework for endocrine disrupters supported by controversial science, suggest 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 and favour, in its place, systemic short-term risk aversion. Inappropriate and disproportionate use of the EU's Precautionary Principle, as well as the use of precautionary legislation and hazard-based regulation, amplifies concerns.

[10] Pelkmans J., and Renda A., 'How Can EU Legislation Enable and/or Disable Innovation?' (CEPS Working Paper for the European Commission, 2014)

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

2.2.2 Market Conditions

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 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.

Well-designed risk management rules can help to shape market conditions favourably in other ways as well. Quality and safety standards, if based on science and risk and developed using expert, technocratic processes, facilitate market access. They also allow for a flexible and proportionate response to new knowledge. In the past, the EU's "New Approach" to regulating consumer safety has achieved this, and has been widely admired[11].

Some academics argue that governments can, under certain conditions, create new markets by using rigorous health and environmental standards to limit the use of some existing products, materials, or technologies. It is suggested that this may also create opportunities for market leadership: a government-led, market-forcing strategy[12]. Evidence to support this is, however, limited and inconclusive. It is a form of mandatory substitution that relies upon statist intervention in markets, ignores the possibility of negative unintended consequences, and assumes that safer or better alternatives will always be available. Whilst there may have been social benefits in a small number of cases, the wider evidence suggests that the use of the so-called "substitution' principle as a tool of industrial policy tends to induce de-localisation of activity to markets with more proportionate rules or the use of older, less safe alternatives[13].

[11] See for example, Pelkmans J., and Renda A., 'How Can EU Legislation Enable and/or Disable Innovation?' (CEPS Working Paper for the European Commission, 2014)

[12] See for example, Porter M.E. and van der Linde C. 'Toward a New Conception of the Environment-Competitiveness Relationship' 9Journal of Economic Perspectives vol. 9, 1995) and Ashford N., Ayers C. and Stone S. 'Using Regulation to Change the Market for Innovation' (Harvard International Law Review, Vol. 9, 1985)

[13] Note the arguments in Lofstedt R. 'The Substitution Principle in Chemical Regulation: a constructive critique' (Journal of Risk Research, October 2013), Lofstedt R. "Risk Versus Hazard – How to Regulate in the 21st Century (European Journal of Risk Regulation, 2/2011), and Nordlander K., Simon C-M, and Pearson H. 'Hazard versus Risk in EU Chemicals Regulation' (European Journal of Risk Regulation, 2/2010)

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, expanding the scale of the market opportunity needed to recover the costs of investment and threatening the value of businesses[14]. When this occurs, innovation investments are distorted and, in many cases, 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, green biotechnology, and productivity-enhancing animal health products[15].

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 hormones in beef cattle, decisions have been based on other, 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.

[14] Many innovation projects require investment over lengthy periods of time. The total cost of such investments includes cash expenditures along with the risk-adjusted opportunity cost of capital. If regulatory factors delay the project, slowing down the point at which the innovation can be placed on the market, or increase the cash costs required, then the total capitalized cost of the innovation increases. The higher the capitalized cost of the project, then the larger the market opportunity that must be exploited, if the value of the business is not to be eroded. Such factors are regularly taken into account in the investment appraisal models used by companies. Regulatory uncertainty, the concern that political or social factors may affect product approval or availability, is also taken into account by companies and further increases capitalized costs. A sectoral example is the model developed by Tufts University in the USA to explain the cost of developing new human pharmaceutical products. Over time, such factors influence the attractiveness of individual investments, as well as the extent of investment in particular regions, particularly when other regions offer more proportionate, evidence-based regulatory frameworks.

[15] Some regulators have become aware of this problem and steps have been taken to reduce the regulatory impact on capitalized cost of new product development. Examples include work by Canada to speed up recognition of FDA approvals of new veterinary medicine products; and actions by the US FDA and EU's EMA to improve the economics of new drug development for human illnesses.

2.2.3 Access to Knowledge and Ideas

Regulation of risk can also affect the creation and diffusion of ideas. This occurs through two different processes: loss of access to established technologies because of regulatory-induced decisions; and diversion of resources away from new ideas because of the cost of 'Defensive' R&D[16].

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. This occurs through the voluntary de-listing of substances by upstream suppliers because of Defensive R&D requirements. 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 contribution margin of a substance then, in general, it will be de-listed. Downstream users will lose access to it, along with all of its 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. In too many instances, decisions taken are politicised, over-precautionary and based on hazard, and of poor quality. This has 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 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[17].

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.

[16] Defensive R&D occurs when new safety, quality, or efficacy requirements must be applied to existing products. The costs of testing, registration et al are normally met out of existing research and development budgets diverting resources away from innovation and towards the 'defence' of existing products.

[17] This process is sometimes described as de-listing due to the high costs 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: capital allocation decisions reflect global norms established by capital markets not the particular exigencies of the EU's regulatory mechanisms. 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. Unless such 'defensive' investment improves market confidence or reduces risk to human health and the environment, then there is no obvious gain for citizens.

Emerging evidence from the initial evaluation of the EU's REACH programme for the management of risks posed by chemical usage highlights the problem. It shows how substantial resources have been diverted away from innovative investment without any material or credible gain for society[18]. Moreover, there has been no improvement in market confidence in the EU because activists have manufactured a succession of controversies about the alleged harms posed by particular chemical materials.

Other sectors have experienced similar problems, most notably animal health, biocides, and crop protection[19].

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.

[18] Centre for Strategy and Evaluation Services 'Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry' (study for the European Commission, 2012)

[19] See for example the quantitative evidence of expenditure on Defensive R&D in Business Decisions Limited 'Benchmarking the Competitiveness of the European Animal Health Industry' (2007). The same study quantifies the impact of regulatory factors on the time needed to develop new animal health products, and, using archetype models, the total capitalized cost needed to bring new products to market. Comparisons with the situation in the USA, highlighting the risk of de-localisation of innovation, are also included.

2.3 EU Innovation Policy - Role of Regulation

Ideally, decision-makers are aware of all of the obstacles to innovation within the business environment, including those created by regulatory processes and decisions. In turn, this knowledge should shape the design of all major policies that seek to promote innovation.

Some of the EU's economic policies acknowledge this:

- *'Europe 2020'*, the EU's flagship policy to promote economic growth, in its 'Innovation Union' section identifies the need to screen regulatory frameworks to provide sufficient and continuous incentives to drive innovation[20];
- The Communication on *'Integrated Industrial Policy'* commits the European Commission to ensure that all policy proposals with a significant effect on manufacturing undergo a thorough analysis of their impacts on competitiveness. This should be undertaken using the existing impact assessment (IA) process and should include, inter alia, an assessment of the overall impacts of a proposal on competitiveness, including cost, price, and innovative implications for industry and individual sectors, as well as consumer satisfaction[21]; and,
- The EU's strategy *'European Industrial Renaissance'*, designed to re-build the manufacturing sector and hence foster growth accepts that manufacturing productivity in the EU is declining and recognises that inflexible administrative and regulatory environments are hampering growth. It recommends, amongst many other measures, an expansion of the scope of the REFIT exercise to consider the cumulative costs of regulatory compliance at the sectoral level and the application of a "competitiveness test" during the IA process[22].

Whilst these commitments are to be welcomed, more needs to be done. There remains an inadequate understanding of the impact of regulation on innovation. In general, the EU's economic policy statements focus on strengthening standards and protecting intellectual property, whilst cutting administrative burden for SMEs. Wider impacts of regulation, through mechanisms such as defensive R&D, stigmatisation, product development costs, or technology choices, are not highlighted. A further problem is the lack of policy coherence. The EU's Smart Regulation policy does not explicitly recognise the importance of understanding the wider impacts of regulatory decisions.

[20] European Commission 'Europe 2020 – A strategy for smart, sustainable, and inclusive growth' (Communication, 2010, COM (2010), 2020)
[21] European Commission 'Integrated Industrial Policy' (Communication 2010)
[22] European Commission 'For a European Industrial Renaissance' (Communication, 2014, SWD (2014) 14)

Political support is inadequate too. Responsibility for the promotion of innovation is splintered across no less than five Commissioners and public statements continue to focus on burden reduction as the primary focus of the regulatory reforms needed to strengthen incentives to innovate[23].

3. Innovation Principle and EU Risk Governance

3.1 Risk Governance

In general, societies make decisions about the management of risks using a two-stage process. In the first stage, political processes determine the potential risks that should be managed by government, as well as the level of social acceptance of risk. Key requirements are then set out in legislation, determining the scope of "public management of risk". At EU-level, these goals are set out in the Treaty and secondary legislation. After this process is concluded, the next stage involves a series of decisions about governance.

For the management of harms this second stage is known as "risk governance", and can be considered to be the way in which governments assess, manage and communicate those risks that citizens believe should fall within the scope of public risk management. It encompasses the wide range of regulatory and administrative measures needed for implementation of political goals and secondary legislation. Moreover, good practices from the OECD and elsewhere, suggest that risk governance should include 'horizontal' principles informing all risk management decisions as well as the key mechanisms of governance, encompassing policies, guidelines, and institutional architecture[24].

Risk governance policies, supported by appropriate guidelines and institutions, ensure that decisions about the management of potential risks take place on a consistent basis, meet accepted standards of good administration, and promote policy coherence. Research by the ERF suggests that the most effective approaches to risk governance go beyond this and seek to ensure that decisions about the management of potential risks deliver high standards of protection whilst, at the same time, maintaining strong incentives to innovate[25].

[23] Note, among others, the Conclusions of the Meeting of the European Council of 14-15 March 2013 and 26-27 June 2014, along with recent appointment of Dr Stoiber, along with his priorities, to assist Vice-President Timmermans, the Commissioner responsible for Better Regulation.

[24] See OECD 'Recommendation on Regulatory Policy and Governance' (2012)

[25] Held under The Chatham House Rule, a series of Risk Forum meetings and policy lunches have been organised by the ERF since 2007 involving academics, senior managers from a wide range of sectors, and officials from all of the EU's institutions, Member State governments, the OECD, and the governments of Canada and the USA.

To achieve this, some governments have begun to develop 'horizontal' practices to structure the process of risk governance. These practices constitute critical success factors that apply to all types of risk management decision and include:

- **Objectives** – ensure that measures have concrete, measurable, and internally coherent goals, and that benefits justify costs and net risks are reduced, after taking account of wider economic and social impacts, as well as other costs and benefits;
- **Risk-taking** – recognise the importance of risk-taking for innovation, economic prosperity and long-term improvements in the quality of life;
- **Science** – base risk management measures on a formal, peer reviewed scientific risk assessment, supported by the highest quality, internationally accepted scientific and technical information available;
- **Innovation** – recognise that the way in which societies choose to regulate risk can affect innovation and ensure that such impacts are assessed explicitly and, wherever possible, moderated or avoided;
- **Countervailing risks** – recognise that risk management measures may, in certain circumstances, create additional risks or amplify existing ones (the "risk-risk" problem)[26];
- **Precaution** – use as one of number of legitimate approaches to making risk management decisions, respecting its limitations and weaknesses, ensuring that its application is restricted to limited and specific circumstances, and employing distinctive, detailed process standards for its application[27];
- **Measures** – design proportionate risk management measures that maximise flexibility and incentives, recognise the role of private markets in creating prosperity, and limit restrictions on choice and freedom; and,
- **Good administration** – develop all forms of risk management measures (laws, rules and substantive guidance) using processes meet internationally accepted standards of good administration. These are – transparency and consistency; public participation; public record; and accountability[28].

[26] Professors John Graham and Jonathan Wiener from Harvard University brought this idea to prominence. See Wiener J. and Graham J. 'Risk versus Risk: Tradeoffs in Protecting Health and the Environment' (1995), and Wiener J. "Managing the Iatrogenic Risks of Risk Management' (Risk: Health, Safety, & Environment 39, Winter 1998). A requirement for officials to consider such impacts ("ancillary benefits and costs") of risk management rules is set out in the US guidelines for undertaking impact assessments – US Office of Management and Budget 'Regulatory Analysis – Circular A-4' (2003)

[27] Canada provides an excellent example. See Privy Council of Canada 'A Framework for the Application of Precaution in Science-Based Decision Making about Risk' (2003). The European Commission has also issued guidance - European Commission' Communication from the Commission on the Precautionary Principle' (2000, Com (2000) 1)

[28] These are described in greater detail in a number of ERF policy documents that highlight the need for the EU to adopt a Law of Administrative Procedures. See for example, ERF 'An EU –Level Law of Administrative Procedures' (Policy Note, 2012)

Alongside these good practices, risk management measures should meet wider governance standards, including proportionality, non-discrimination, and consistency.

3.2 EU-Level Risk Governance Framework

At EU-level, the approach taken to risk governance is complex. Detailed sector-specific requirements and related governance processes, including the provision of scientific advice, co-exist with a small number of 'horizontal' risk management principles, a policy on collection and use of evidence, the requirements of the Precautionary Principle Communication and general governance standards, forming part of the Smart Regulation strategy. All measures, with the exception of substantive guidance (specifying technical or scientific standards for compliance), are required to meet the Commission's impact assessment and consultation standards, for instance.

Looking at risk governance specifically, the following requirements apply at EU-level:

- **General risk management principles –** all risk management measures should, according to Commission guidance, satisfy five general principles. They should demonstrate proportionality between the measures taken and the chosen level of protection. They should be non-discriminatory in application and should be consistent with measures already taken in similar situations. Benefits and costs of action, or lack of action, should be considered, and measures should be reviewed in the light of scientific developments[29].

  Taken together, these are, with the exception of the requirement to review a measure if there are scientific developments, general statements of governance; they are not specific to the governance of risk.

- **Precautionary Principle** – the possibility to employ this as a means to manage risks to human health and the environment is set out in the Treaty. The Commission produced guidelines for its application in 2000[30]. According to the Communication, the principle may be invoked when a phenomenon, product or process may have adangerous effect, identified by a scientific evaluation, and any assessment does not allow the risk to be determined with sufficient certainty. Action may then be taken, depending on the level of risk. As a part of the risk management stage of protection

[29] These principles form part of the Precautionary Principle Communication – see European Commission' Communication from the Commission on the Precautionary Principle' (2000, Com (2000) 1) They are described as being general principles not limited to application of the precautionary principle and as such applying to all risk management measures.

[30] European Commission' Communication from the Commission on the Precautionary Principle' (2000, Com (2000) 1)

against potential risks, any measures justified by the Precautionary Principle must meet the standards set out in the Commission's general risk management principles (see above).

Whilst this is a 'weak' form of the Precautionary Principle in that it does not mandate bans whenever any uncertainty is present, the thresholds for its application are ill defined, creating opportunities for politicisation and regulatory unpredictability[31]. In practice, moreover, the presence of the Precautionary Principle in the EU's risk governance framework has promoted the use of hazard-based laws for the management of potential risks and institutionalised precaution in implementation processes.

A track record of poorly justified, controversial decisions, justified by recourse to the Precautionary Principle, has also been built up. This has undermined the confidence of businesses and investors. Incentives to invest in technological innovations, that are invariably associated with higher risks, have been eroded.

- **Scientific advice** – this is provided to the Commission through a wide range of different sources: EU agencies and related scientific committees and panels; technical working groups; ad hoc studies, some conducted by outside consultants; the Joint research Centre; and the three independent scientific committees reporting to DG SANCO. Each source provides advice on the basis of different standards and policies, many determined by risk governance requirements set out in sectoral legislation.

  Overarching requirements are limited to those set out in the Commission's Communication on the collection and use of expertise[32]. This provides limited guidance. It focuses on evidence gathering processes and requires them to meet standards of quality, openness and effectiveness. However, details of how to achieve high standards of information quality are not provided, leaving major gaps on the 'horizontal' risk governance framework. Standards of scientific evidence and other issues of information quality are not defined; issues of bias, including the influence of activist scientists, are not addressed; and there is no requirement for significant risk assessments, upon which legislation, regulation, or guidance is based, to be peer reviewed[33].

[31] An important critique is set out in Majone G. 'What Price Safety? The Precautionary Principle and its Policy Implications' (Journal of Common Market Studies, Vol. 40, 2002)

[32] European Commission 'Communication on the collection and use of expertise' (2002)

[33] This involves an independent review of the evidence and findings of important risk assessments. Public notice and comment processes are used to highlight areas of concern but an independent panel undertakes the review. The importance of independent peer review, as a mechanism for assuring the scientific quality of risk assessments, has been fully recognized in the USA, for instance. Requirements for federal agencies are set out in the US OMB 'Final Information Quality Bulletin for Peer Review' (2004). The guidance set out in the bulletin aims to increase the quality and credibility of scientific information generated across the US government.

Some examples of good practices have, however, emerged. Using powers set out in the relevant Commission Decisions of 2004 and 2008[34], officials have drawn up new, binding rules of procedure for the three independent scientific committees that support the work of the EU's institutions. These require risk assessments to meet best international standards; be based on the best data, scientific knowledge, and methodology available at the time of the preparation of an opinion; and be quantified if practical. Advice must not consider social acceptance of risk and must also not be influenced by any consideration other than scientific assessment of risks, and this implies independence from conflicts-of-interest and bias[35]. These requirements represent the beginning of the emergence of standards for scientific quality and risk assessment at EU-level[36].

- **Sector-specific requirements –** many laws designed to protect citizens and the environment focus on specific sectors or technologies. There are, for example, laws dealing with biocides, chemicals, or genetically modified organisms, plant protection products, cosmetics, veterinary medicines and foodstuffs. Most of these laws set out elements of the key processes that must be used to assess and manage risks. This is not, however, based on any consistent, 'horizontal' approach to risk governance.

  An example of sector-specific risk governance can be found in the EU's General Food Law[37]. Its objective is the protection of consumers. It requires measures to be based on risk analysis. Risk assessment, the initial phase of the decision-making process, should be based on the best available scientific evidence and undertaken in an independent, objective and transparent manner by an EU agency, the European Food Safety Agency (EFSA). Risk management should take account of the findings of the risk assessment phase and other legitimate factors, including, where conditions are relevant, the Precautionary Principle. Throughout the process of developing measures, there should be open, transparent consultation. There is, however, no mention of taking account of innovation either as an objective of legislation or when considering risk management options.

This short overview suggests that, despite some examples of good practice, the EU's overall approach to risk governance is fragmented and incomplete. 'Horizontal' requirements are limited, with the exception of the Precautionary Principle, to general principles of regulatory governance. As a result, there has been a tendency, over time, for precautionary

[34] European Commission' Commission Decision setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health, and the environment' (2008). This repealed the original, founding Decision of 2004.

[35] European Commission DG SANCO 'Rules of Procedure of the Scientific Committees on Consumer Safety, Health, and Environmental Risks, and Emerging and Newly Identified Health Risks' (2013)

[36] European Risk Forum 'Science and Decision-Making – Balancing Excellence and Independence' (Policy Note 22, 2013)

[37] EC Regulation 178/2002 'General principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety'

ideas to have a disproportionate influence on the development of risk governance and on the design of risk management legislation.

'Horizontal' risk governance requirements are critical for ensuring high quality decision-making during the implementation phase of risk management. They structure the activities of the 'administrative state', providing consistency, predictability, and policy coherence. At EU-level, the lack of such a framework contributes to the poor quality of many decisions taken to implement laws designed to manage potential risks.

3.3 EU Risk Governance and Innovation - An Assessment

At EU-level, there is a lack of clarity as to the importance of considering the impacts on innovation of risk management measures. Some statements, action, and policies are supportive, whilst others are not.

Evidence of support for the need to consider links between innovation and risk management is, however, limited and includes:

- **Political Statements** – President Juncker highlighted the need to take risks, in order to make Europe more competitive, when addressing the European Parliament at the beginning of his presidency of the European Commission in 2014[38].

  Such statements are essential. If made consistently and without other contradictory observations, they begin to frame political attitudes that are supportive of innovation. Unfortunately, other actions and statements by the European Commission question some of the premises on which investment in innovation is based, most notably the importance of science in decision-making.

- **Political Guidelines for the 2014-2019 Commission** – these recognise the importance of the regulatory environment for promoting entrepreneurship and job creation, and urge officials to avoid stifling innovation and competitiveness with too prescriptive and too detailed regulations. It then goes on to require regulators to cut 'red tape'.

  Whilst this is encouraging as a quasi-political statement, it is not a substitute for a formal risk governance framework. Moreover, its focus is on SMEs and administrative burden rather than the wider impacts of risk management and the allocation of capital to innovation. It remains, regrettably, anchored in the regulatory policy debates of the early 1990s.

[38] Speech by President Juncker to the European Parliament in July 2014 ('A New Start for Europe')

- **'Competitiveness Proofing'**[39] – this has been added to the impact assessment requirements for all measures. It requires the impact of any measure on innovation to be considered.

  This is probably the strongest policy requirement put in place so far by the EU, and is to be welcomed. Its strength is its focus on one of the wider impacts of regulation. It is not, however, a form of risk governance. Instead, it requires a more complete assessment of regulatory impacts as part of the process of informing decision-makers rather than guiding officials whenever they are designing any form of risk management measure, including rules and administrative actions (such as substantive guidance). Moreover, to be effective it needs to be supported by detailed guidance that explains how regulations might affect innovation: these are incomplete.

- **Impact Assessment Guidelines** – the latest guidelines, developed in 2014, require impacts of proposed measures on innovation to be considered, along with a long list of other potential social, economic, and environmental impacts. They also require impact assessments to be based on the best available evidence and scientific advice, building on other policy commitments made by the Commission, as part of the Smart Regulation Communication in 2010, to make use of evidence-based decision-making. The scope of the impact assessment has been expanded as well. In the future it will apply to significant implementing measures, as well as policies and legislation.

  These requirements provide an operational structure and process for applying the competitiveness 'test' developed by the Commission, and represent an important step forward. They are, however, incomplete. Formal guidelines for risk management measures, one of the most important policy areas at EU-level, have not been developed: a major gap in the IA process. The required assessment of the impact of regulations on innovation fails to adequately consider important problems such as risk aversion, Defensive R&D, and higher capitalised costs of product development. Finally, the Innovation Principle has not yet been included as one of the new, 'horizontal' tests that must be considered for all proposed measures[40]. The European Risk Forum proposes that this should be done and argues that this will help to stimulate confidence in the private sector to invest in innovation.

[39] European Commission 'Integrated Industrial Policy' (Communication 2010)

[40] Ideas for overcoming these problems by reforming the Commission's IA guidance are included as Appendix A. They build on the ERF's contribution to the Commission's public consultation of 2014 on proposed changes to the IA guidelines.

Although these statements and policies are encouraging they do not go far enough[41]. At EU-level there is no formal 'horizontal' framework for risk governance that meets best practice standards, that requires innovation to be considered when developing measures, and that ensures precaution is used proportionately.

A further problem is the splintered and complex organisational focus on innovation within the Commission. It does not form part of the scope of the portfolio of Vice-President Timmermans, the Commissioner responsible for Better Regulation or within the portfolio "Internal Market, Industry, Entrepreneurship and SMEs". Instead it appears as an explicit responsibility in the portfolios of five other Commissioners: Commissioner Ottinger (Digital Economy and Society); Commissioner Canete (Climate Action and Energy); Commissioner Bulc (Transport); Commissioner Moedas (Research, Science, and Innovation); and, Commissioner Novracsics (Education, Culture, Youth, and Sport). Within this group, Commissioner Moedas (Research, Science and Innovation) is tasked with ensuring that policies are developed that will ensure the conversion of research into more investment, jobs, and growth. Such a requirement rightly reflects the importance of this aspect of the governance of innovation.

Without a clear organisational focus on innovation at the political-level within the European Commission, it is difficult to garner the support needed for the development of policies, guidelines, and institutions needed to bring together risk management and innovation, and to embed the Innovation Principle into decision-making.

Finally, a number of statements and actions by the Commission appear to question the importance for innovation of high quality risk management measures. Under President Barroso, the European Commission appointed a Chief Scientific Advisor (CSA) to oversee standards of scientific evidence used in the legislative cycle and to help transmit scientific evidence to policy-makers. Such an institutional change sent out a powerful, positive message to investors in innovation. Regrettably, the new Commission has not been continued this position. Although Commissioner Moedas has been asked by President Juncker to examine options to ensure that Commission proposals are based on scientific evidence, the decision to dismantle the office of the CSA has created significant concerns amongst both the scientific community and the private sector about the continued commitment of the EU to base risk management measures on high quality science[42]. President Juncker's comments about the desirability of reducing the importance of science in decisions about GMOs amplify such concerns[43].

[41] Another encouraging development is the decision by President Juncker to appoint to two external experts to the Commission's Impact Assessment Board, the institution responsible for oversight of impact assessments produced by the Commission. If appropriately chosen, these experts could bring greater awareness to the IA process of the impact of risk regulation on innovation.

[42] The EU Chief Scientific Adviser's role and importance has been the subject of a special issue of the European Journal of Risk Regulation – see EJRR, Vol. 3, 2014

[43] European Commission 'Political Guidelines for the 2014-2019 Commission' (2014)

4. Areas for Improvement

Urgent action is needed to build on the EU's Better Regulation initiatives and processes, so as to find ways to ensure that innovation is considered fully whenever the EU's institutions consider policy' legislative, or regulatory measures. The ERF has raised awareness of this and championed the adoption of the "Innovation Principle" by the EU's institutions. The next challenge is to find ways to embed this principle into the EU's decision-making processes. This will require major changes in the EU's policies, guidelines and institutional architecture.

Any recommended changes will need to tackle a number of areas of concern where improvement is essential. Specifically:

- **Promotion of innovation lacks political focus or accountability.** It is splintered across a number of European Commissioners, making it difficult to ensure that policy is coherent and, moreover, that it takes account of all of the obstacles to innovation, including the way in which the EU regulates potential risks.
- **Policy coherence is weak, because there is no political link between Better Regulation and the promotion of innovation.** The portfolio of the Commissioner responsible for Better Regulation makes no mention of the importance of understanding the wide impacts of regulation, most notably the impact of risk management on innovation. It is essential to address this because technologically based innovation is almost always associated with some form of risk. In the light of this, regulations that seek to avoid risk tend to undermine confidence and to limit investment in innovation.
- **Political commitment to evidence-based decision-making, the foundation stone of modern regulation of risk and innovation, appears to be weakening.** Recent actions and statements by the EU's institutions suggest that science is no longer seen as the most important input for making risk management decisions. Instead, it is seen in a post-modern light as one of a number of opinions that may have some influence on risk management outcomes. Regulatory decisions made on this basis are politicised and unpredictable, eroding incentives to innovate.
- **Economic policies fail to recognise fully the complex impacts of the regulatory framework on innovation.** Most accept the importance of innovation for the future prosperity of the EU, yet there is little recognition of the importance of the regulatory framework as a determinant of innovation, apart from protecting intellectual property, promoting standards, and reducing 'red tape' and regulatory burden for SMEs. This is the agenda of the early 1990s. There is a failure to recognise the wider impacts of risk management laws. The contribution that the Commission's Better Regulation strategy can make towards fostering innovation

should not, therefore, focus solely on cutting administrative burdens.

- **Regulatory policy is incomplete: there are major gaps.** The Smart Regulation policy, the EU's flagship policy for regulatory decision-making, lacks an explicit focus on the relationship between innovation and regulation or on the role of science in decision-making.
- **Risk governance policy at EU-level places a disproportionate emphasis on precaution, as well as being fragmented and incomplete.** 'Horizontal' requirements and practices are, with the exception of the Precautionary Principle, limited. As a result, there has been a tendency, over time, for precautionary ideas to have a disproportionate influence on the development of risk governance and risk management legislation
- **Policies for assuring the quality of scientific evidence used to support decision-making are incomplete and do not meet best practice standards.** Details of how to achieve high standards of information quality are not provided, leaving major gaps on the 'horizontal' risk governance framework. Standards of scientific evidence and other issues of information quality are not defined; issues of bias, including the influence of activist scientists, are not addressed; and there is no requirement for significant risk assessments to be peer reviewed.
- **Impact assessment guidelines do not focus adequately on the need to consider innovation or upon the relationship between risk management and incentives to innovate.** Formal guidelines for risk management measures, one of the most important policy areas at EU-level, have not been developed: a major gap in the IA process. The impact of regulations on innovation fails to adequately explain important problems such as risk aversion, Defensive R&D, and higher capitalised costs of product development. Finally, the Innovation Principle has not yet been included as one of the new, 'horizontal' tests that must be considered for all proposed measures.

5. Recommendations[44]

Action is needed at EU-level to build on its world-leading regulatory management processes and to establish a revised framework of policies, guidelines, and institutional structures that embeds the Innovation Principle into the EU's decision-making processes for making risk management decisions.

When developing new institutions, policies, and guidelines, the EU should make full use of ideas developed in other parts of the OECD area and within the Member States. Canada, for instance, sets out principles to guide regulators. One of them requires the government when regulating to promote a fair and competitive economy that encourages entrepreneurship, investment, and innovation[45]. Policies in the USA lay down similar requirements, requiring regulators to develop a regulatory system that both ensures protection and improves the performance of the economy. Regulators are also expected to recognise that the private sector and private markets are the best engines of economic growth[46]. Australia, in contrast, has taken a different but complementary approach, focusing on institutional reform. The Australian Productivity Commission, an independent body with statutory authority, focuses on reviewing micro-economic policy, including regulatory requirements, so as to help the Commonwealth government make better policies. Its recommendations are highly influential, and exploit the expertise of regulators and of the private sector.

EU-level reforms should focus on using this experience along with other ideas to find ways to embed the Innovation Principle into decision-making but within an overall approach to managing potential risks based on high quality scientific evidence. Reforms should, moreover, ensure that the improved approach uses science and evidence to protect citizens and the environment, balances precaution and proportion, and strengthens incentives to innovate.

[44] These recommendations focus solely on the link between innovation and the regulation of risk. They set out reforms designed to achieve an appropriate balance between ensuring a high standard of protection and sustaining incentives to innovate. As such, they form only one part of the range of policy measures that governments take to promote innovation. Other measures focus on issues such as R&D funding, relationships between the private sector and the science base, availability of risk capital, education and skills, and public procurement.

[45] Canadian Privy Council Office 'Cabinet Directive on Regulatory Management' (2012)

[46] US Executive Order 12866 'Regulatory Planning and Review'; issued originally by President Clinton in 1993, it was confirmed by President Obama.

To achieve these goals whilst overcoming existing weaknesses, the ERF has identified a series of recommendations in four areas:

- Political Commitment (section 5.1.);
- Institutional Architecture (5.2.);
- Formal Policies (5.3.); and,
- Guidelines (5.4.)

5.1 Political Commitment by the EU Institutions

5.1.1 Political Recognition of Links Between Innovation and Regulation

Recommendation 1 - Issue political statements stressing the importance of ensuring the proper consideration of productivity, innovation and wider impacts, such as jobs, growth, and competitiveness, in the legislative and regulatory decision-making process. These statements should demonstrate the commitment to innovation of the Commission, Parliament, and Commission.

Recommendation 2 – Create a common cross-institutional working group, drawn from all three EU institutions, focusing on the promotion of innovation at EU-level and recognising the joint responsibility for supporting better regulation, risk-taking, and innovation.

5.2 Institutional Architecture of the European Commission

5.2.1 Political Responsibility for Innovation

Recommendation 3 - Revise the scope of the portfolios of the Commission Vice Presidents, such that one of them has overall responsibility for the promotion innovation. This should be a formal appointment. Specifically, the "Vice-President for Innovation" should:

- Take political responsibility for establishing and achieving the EU's innovation objectives;
- Establish a single, "horizontal' policy for the promotion of innovation, pulling

together all of the different existing strands including relevant regulatory reforms;

- Set up a permanent advisory group of stakeholders;
- Identify and disseminate best practices for innovation policies;
- Create and co-ordinate a network of "innovation champions" in each DG. These should be senior officials within a DG and will be responsible for ensuring the coherence of policies, laws and rules with the EU's innovation objectives; and,
- Publish an annual report explaining progress in promoting the EU's innovation objectives. This should build on and expand the existing Innovation Scorecard. It should highlight explicitly improvements in the regulatory framework designed to reduce obstacles to innovation.

5.2.2 Political Responsibility for Better Regulation and Innovation

Recommendation 4 - Expand the scope of the Better Regulation portfolio of Vice-President Timmermans to require the wider impacts of regulation to be understood and managed, including the impact of risk management regulation on innovation. This should include taking the following steps;

- Revise the Smart Regulation Communication (see Recommendation 9);
- Draw up a new, 'horizontal' regulatory policy (see Recommendation 10);
- Establish a formal risk governance policy (see Recommendation 11); and,
- Expand the REFIT programme to encompass formal assessments of the impact of risk regulation on innovation (see Recommendation 16).

5.2.3. Oversight and Accountability for Regulatory and Risk Governance Policies

Recommendation 5 – Create an institutional structure close to the centre of government with responsibility for ensuring adherence by all Commission Services and agencies with the new Regulatory and Risk Governance Policies. This group should report to a senior, permanent official at Director-level within the Secretariat-General.

5.2.4. Oversight and Accountability for Scientific advice

Recommendation 6 – Establish an institutional structure close to the centre of decision-making with responsibility for assuring the quality of scientific advice used to inform risk management decisions throughout the European Commission. This new group, led by a senior, permanent official at Director-level within the Secretariat-General or a new Chief Scientific Adviser reporting directly to the President of the Commission, should:

- Draw up and enforce a new' horizontal' policy for the provision of scientific advice (see Recommendation 12);
- Draw up a new policy for recognising and managing the potential risks posed by new technologies (see Recommendation 13);
- Establish a steering group to provide guidance and to oversee and co-ordinate the use of science by the Commission, its agencies, and its technical working groups;
- Create a network of senior scientific advisers located in each DG;
- Be represented on the Impact Assessment Board of the European Commission; and,
- Promote and co-ordinate a network of equivalent institutions at MS-level, and maintain close contacts with national standards bodies and scientific institutes so that the best science is used in decision-making throughout the EU.

5.2.5. Oversight of Impact Assessment

Recommendation 7 – Revise the mandate of the Impact Assessment Board to ensure greater focus on the linkages between Better Regulation, innovation, and Europe 2020. The newly appointed outside experts could help strengthen the focus on the impact of risk regulation on innovation.

5.3 Formal Policies of the European Commission

5.3.1. Innovation Principle Communication

Recommendation 8 - Issue a formal Commission Communication establishing the Innovation Principle as one of the main factors to be considered whenever the EU institutions consider policy, legislative or regulatory interventions.

5.3.2. Smart Regulation Communication

Recommendation 9 - Revise the Smart Regulation Communication and require officials to consider fully the wider impacts of legislative and regulatory interventions, including links between the regulatory framework and regulatory processes and innovation.

5.3.3. Regulatory Policy

Recommendation 10 - Establish a formal regulatory policy framework, in the form of a Commission Communication, to support innovation in Europe based on the principles of:

- Science based risk assessment and management;
- Balance and proportionality together with precaution;
- Reduction in regulatory burdens, in line with the conclusions of the May 2013 Competitiveness Council;
- Full inclusion of relevant expertise;
- Transparency of information and evaluation processes; and,
- Protection of commercially confidential information.

5.3.4. Risk Governance Policy

Recommendation 11 - Establish a formal risk governance policy based on the principles of described in this report (objectives, risk-taking, science, innovation, countervailing risks, precaution, measures, and good administration). It should apply to all risk management measures including legislation, regulation, and administrative decisions (including substantive guidance). The policy should be issued as formal Commission Communication supported by appropriate guidance notes.

5.3.5. Scientific Evidence and Advice Policy

Recommendation 12 - Establish a revised policy for scientific evidence supporting public risk management decisions. The principles and standards of this new Commission Communication should have a presumption favouring studies that have been quality assured and performed in accordance with internationally accepted protocols and require sufficient

transparency to facilitate reproducibility. They should require studies, information, and data to be based on widely accepted and objective practices (most notably the "scientific method", with particular emphasis on reproducibility). They should require legislative and regulatory decisions to be based on the best available scientific evidence and should emphasise the paramount importance of 'excellence'. Significant risk assessment should also be subject to mandatory peer review, so as to ensure excellence and legitimacy.

Standards of scientific advice should define tests of objectivity that encompass both 'bias' and conflict-of-interest', recognising the need to gain access to all sources of expertise, including that funded by the private sector; and they should require studies and data to be assessed on the basis of scientific quality and on demonstrable relevance to real-world conditions.

Finally, the policy should provide a comprehensive set of key concepts and definitions used in the provision of scientific advice, including definitions of 'best available science', the 'scientific method', 'uncertainty', 'hazard', 'risk', and 'reproducibility'.

5.3.6. New Technology Policy

Recommendation 13 – Develop a formal policy for identifying and managing the potential risks posed by new technologies. This new Commission Communication should require risk management legislation to be technologically neutral and should recognise the negative consequences for innovation of stigmatising new ideas and locking-in old technologies. Moreover, the policy should also require implementing rules and substantive guidance, including risk assessment and risk management requirements, to be application specific, derived from high quality evidence, and based on realistic understanding of risk and exposure.

5.4 Guidance for the European Commission

5.4.1. Impact Assessment Guidelines

Recommendation 14 – Implement the following amendments to the Commission's impact assessment guidelines:

- Include the "Innovation Principle" in the list of horizontal priorities to be covered by all impact assessments;
- Expand the guidelines to include a specific annex describing the best way to

carry out impact assessments when assessing proposal to manage potential risks, recognising that, in accordance with the guidance set out the Commission's 2000 Communication, the Precautionary Principle is only applicable in very limited number of cases. (Further ideas, describing the possible contents of such an annex, are included in Appendix A.);

- Revise the scope of the application of the guidelines to include major agency decisions and substantive guidance used to implement secondary legislation;
- Recognise within the guidance the increasing use of stigmatisation, blacklists, substitution and other 'soft' tools to manage risks, highlighting strengths and weaknesses. Any guidance should recognise that these risk management measures seek to influence product market decisions on an extensive scale, with potentially significant unintended consequences for innovation, competitiveness, jobs and growth;
- Require officials to place greater emphasis on understanding more of the complex impacts of modern regulatory actions on businesses and citizens. Such impacts include problems of demand stigmatisation, barriers to dissemination of new "general purpose technologies", Defensive R&D, and other impacts on innovation;
- Revise the description of the impact of regulations on innovation, recognising the importance of strengthening risk acceptance, minimising increases in the time and cost needed to develop new products, limiting losses of well-established materials and innovative resources (due to Defensive R&D), and minimising distortions of product market activity;
- Require officials to formally identify and assess the wider costs and benefits of proposed measures, including countervailing risks and impacts on innovation; and,
- Draw up a technical 'toolkit' for officials to help them understand potential impacts of regulation on innovation.

5.4.2. Ex Post Evaluation Guidelines

Recommendation 15 – Revise the Ex Post Evaluation guidelines, and implement the following changes:

- Require an obligatory ex post evaluation of the effectiveness of risk management legislation, regulation or administrative decisions where new evidence becomes available to demonstrate an acceptable balance of risk or other evidence demonstrates no material impact on the issue originally identified as giving rise to concern;

- Examine the impact of the regulatory framework (including decision-making processes and substantive guidance) on innovation, whenever a legislative decision is evaluated; and,
- Identify horizontal lessons from the ex post programme that help officials understand the wider impacts on regulation on innovation. These lessons might include the impact of regulations on market access, product development economics, product availability, access to ideas, and innovative resources.

5.4.3. REFIT Guidelines

Recommendation 16 - Implement the following changes to the REFIT guidelines:

- Initiate an in-depth examination of the impact of the regulatory framework (including decision-making processes and substantive guidance) on innovation in each sector subject to review. As a part of this, it may be appropriate to use cross-country benchmarking when considering issues such as Defensive R&D or product development economics.

European Risk Forum

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

Appendix A

Impact Assessment Guidelines and Risk Management Measures

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. Today, it is most readily associated with government actions to protect people at work and to protect citizens and the environment from risk. But as a core function of government, risk management has been a potent and pervasive form of public policy for more than 200 years. In that period it has been used to support a range of varied policy objectives, most notably creating the conditions for economic prosperity by managing risks to trade and investment; protecting industrial workers from the impacts of economic activity; and protecting citizens and the environment from ruinous risks.

Public risk management can be broadly defined as any government action designed to prevent, reduce, or re-allocate risk. It includes actions to manage risks posed by technologies, economic activity, and lifestyle choices.

The EU's institutions, along with governments in most other modern economies, have progressively expanded their risk management responsibilities. These now encompass issues such as product safety, food safety, pharmaceuticals, chemicals, environmental protection, public health, occupational health and safety, and consumer protection.

Despite this, the Commission's IA guidelines provide only limited advice about how to make the most effective use of impact assessment, when seeking to manage risks posed by technology or lifestyle choices. Within the guidelines more emphasis needs to be placed on the distinctive nature and importance of this 'horizontal' theme of EU-level policy-making.

Specifically, the following improvements could be made to the Commission's draft IA guidelines:

Problem Definition:

- **Require all legislative, regulatory, and guidance proposals designed to manage lifestyle or technological risks to human health, public safety, or the environment to be accompanied by the findings of formal scientific risk assessment**, designed to support analyses of problem definition and regulatory options, and meeting internationally accepted standards;
- **Recognise the characteristics of different types of threats (including**

lifestyle and technological risks), define them on the basis of scientific knowledge, and take account of this in assessing problems, identifying risk management options, and assessing the costs and benefits of policy action;

- **Base all scientific risk assessments on the best available scientific and technical information**, and ensure that conclusions about a problem's potential risks to human health, public safety, and the environment assessments take full account of the weight of scientific evidence. Assessments should, moreover, distinguish clearly between 'hazard' and 'risk', identify realistic exposures to hazards; and highlight scientific uncertainties (using well-established typologies of different types of uncertainty); and,
- **Require risk assessments to be subject to peer review** if they are to be used to support major legislative, regulatory or administrative decisions.

Objectives:

- **Require objectives for new or revised EU-level risk management rules to recognise the importance of risk-taking** for innovation, economic prosperity and long-term improvements in the quality of life; and, to accept that zero risk is neither achievable nor desirable in modern societies and that legislation cannot achieve this; and,
- **Base objectives on quantified improvements in health or the environment,** requiring officials to demonstrate a clear and credible link between problem, action, and result.

Policy Options:

- **Highlight precaution as one of a number of legitimate and distinctive approaches to risk management decision-making but recognise its weaknesses** and require its use to be cost-effective, based on scientific evidence, proportionate, limited in scope, non-discriminatory, consistent with international agreements, and provisional. The IA guidelines should, for instance, highlight the limited and specific circumstances in which the precautionary principle should be considered as a potential option for managing risks at EU-level.

Assessment of Impacts:

- **Require officials to make extensive use of quantitative analyses when assessing the costs and benefits of different risk management options**. These should include, wherever appropriate, monetary analyses and the use of modern cost effectiveness analyses. Assessments of potential benefits and costs should, moreover, recognise potential unintended negative consequences, and the loss of existing benefits, of specific policy options.

Comparison of Options:

- **Recognise that risk management decisions can, under certain circumstances, create negative unintended consequences,** and require risk managers to take this into account when assessing options (the "risk-risk" problem);
- **Examine the 'workability', 'effectiveness' and 'legitimacy' of new risk management tools and mechanisms, including substance-based substitution, precaution, and direct restrictions on lifestyle activities.** The IA guidelines should include, for instance, a comprehensive description of the problems associated with using hazard-based strategies, such as the Precautionary Principle, to manage risks; and,
- **Consider issues of social acceptance of risk openly and rigorously during the process of comparing different risk management options,** using scientific evidence to distinguish between threats of harm and perceptions of risk. IA guidelines should require officials to provide an assessment of likely risk acceptance and to highlight relevant evidence used to support such analyses.

Appendix B

Impact Assessment, Innovation and the Regulation of Risk – Technical Issues for Regulators

General Principles

As part of ex ante and ex post assessments of measures, officials are required to consider potential benefits and costs, including wider impacts. When assessing the impacts on innovation of measures designed to protect citizens or the environment from risk, officials should bear in mind the following:

- Innovation is the principal driver of productivity in modern economies. Productivity growth is essential for higher wages, more employment, and better living standards. In the light of this and given the EU's economic weaknesses, officials should pay particular regard to any likely impact of a measure on innovation, exploring possible costs and benefits extensively and rigorously.
- Decisions by companies are the most important determinant of innovation in any open, liberal economy. This must be recognised in any programme of consultation and when weighing up the importance of different sources of evidence. Companies should, moreover, be consulted very early in the process of developing measures, so that possible impacts on innovation can be highlighted.
- Multi-national companies are disproportionately important for innovatory activity because of the scale of their investment in R&D, their use of wide range of technologies, and their inter-actions with suppliers. Such companies make sophisticated choices about the allocation of capital, using modern corporate finance models. Their choices embrace not only whether to invest in innovation projects at all but also where to do this and which technology to exploit. Officials should be aware of this and avoid supporting measures that erode the relative attractiveness of the EU as a location for innovation or for the use of new technologies. If necessary, officials should seek to make comparisons between the EU and business environments elsewhere in the world.
- Governments can help the process of innovation by strengthening the "Framework Conditions" for innovation. Measures should be assessed against their impact on these factors, using early consultation to guide the work of officials.
- Regulation of risk affects three of the Framework Conditions for innovation: public attitudes (especially towards risk-taking, new technologies, and entrepreneurship); markets, including access to markets and retention of existing products; and access to ideas, encompassing availability of resources to invest in innovation and continued use of embedded innovation in existing products. Impact assessments

should examine the impact of proposed risk management measures on each of these factors.

- Risk management measures are, by their nature, designed to trigger behavioural changes in citizens or companies or both. Good impact assessment identifies these fully and recognises the likelihood that some changes will be unintentional and that some will produce costs. In some cases, this may affect incentives to innovate.

- Recently, there has been an increased use of risk management mechanisms designed deliberately to trigger extensive changes in behaviour by companies and citizens. Such mechanisms include the "substitution principle", public blacklists, market stigmatisation, and restrictions on usage designed to 'force' innovative activity. Many are used within a framework of hazard-based decision-making.

  Officials should be sceptical about the claimed benefits of such mechanisms and should be alert to possible wider impacts, particularly on incentives to innovate. These new mechanisms are, in general, untested and uncontrollable: in liberal economies governments cannot control how private businesses will respond to such stimuli. All such mechanisms generate negative unintended consequences. Decision-makers should be made aware of these issues.

- Officials should be cautious about supporting any technology-specific risk management measure. Evidence shows that this, in general, acts as an obstacle to innovation. It may even act to inhibit the dissemination of new "General Purpose Technologies": the growth platforms of the future.

- When assessing new risk management measures, officials should consider ex post evidence from other sectors with similar characteristics. Evidence of this type is rarely used in the impact assessment process despite its widespread availability in mature, extensively regulated economies. For instance, any measure that proposes to increase the time or cost of investing in new products should be assessed using 'analogue' evidence from the animal health and novel food sectors.

- Officials should look carefully at the design of risk management measures. Incentives to innovate are likely to be strengthened if measures are performance-orientated, predictable, science-based, and justified by credible assessments of risk. Moreover, market distortions should be limited.

- Risk management measures that propose to impose new or additional safety, quality, or efficacy standards on existing products, thereby triggering expenditure on Defensive R&D regardless of any credible risk, should be assessed particularly carefully.

  Evidence from a wide range of sectors shows that this has serious negative impacts on innovation in the EU: resources for new ideas are diverted into maintaining existing technologies; downstream users lose access to embedded ideas because

producers de-list products; final users lose access to established benefits due to de-listing; and the EU becomes less attractive for innovation because other countries tend to require such additional testing only when proper risk assessment demonstrates an unacceptable threat of harm to citizens or to the environment.

- When assessing risk management measures, officials should highlight any value chain impacts. These occur when regulatory measures change the behaviour of up-stream suppliers of materials or substances. In some cases, for instance, up-stream sectors will be small in scale but their downstream impacts will be extensive. Regulators should identify the extent to which jobs and wealth in downstream sectors depend on the output of upstream producers. Two very good examples are the value chains supported by the Fragrance and Polycarbonate industries.
- Most risk management measures are implemented through an extensive range of legal and administrative processes and decisions. These processes should be examined as part of the impact assessment process because they have a disproportionate impact on incentives to innovate. Implementing processes that rely upon large numbers of technical guidelines or derogations or other forms of administrative discretion are unlikely to promote innovation. This should be made clear to decision-makers.
- Precaution forms a part of the approach taken to the management of risk in most OECD countries. It is, for example, the primary mechanism for managing risks posed by pharmaceutical technologies to humans and animals. At EU-level, a formal Precautionary Principle guides application of this approach. Officials should ensure that all risk management measures justified on the basis of the EU's Precautionary Principle (PP) fully satisfy the conditions for its use in the relevant Commission Communication. Officials should also be aware of the strengths and weaknesses of the PP, including its impact on innovation. These issues should be communicated to decision-makers.

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.

For more information visit www.riskforum.eu or contact:

Dirk Hudig

Secretary-General

European Risk Forum

Rue de la Loi 227

B-1040, Brussels

Belgium

Tel: +322 613 28 28

Fax: +322 613 28 49

Mobile: +32 477 510834

dirk.hudig@riskforum.eu

European Risk Forum ▪ Rue de la Loi 227 ▪ B-1040 Brussels ▪ Belgium
Tel.: +32 2 613 28 28 ▪ E-mail: info@riskforum.eu ▪ Web: www.riskforum.eu