INNOVATION, NOVEL REGULATORY PHILOSOPHIES AND BETTER REGULATION

HIGHLIGHTS NOTE 25

- **This Highlights Note forms part of the ERIF contribution to the new Commission's Better Regulation Agenda.[1] It focuses on the impact of the regulatory framework on incentives to invest in innovation.**
- **Existing failings in the regulatory framework weaken the framework conditions for innovation in the EU. Without reform, the adoption by the EU of new ways of managing risk (Novel Regulatory Philosophies) will exacerbate these failings, making it more difficult to bring forward the innovations needed to deliver greater prosperity and the green transition.**

BACKGROUND

Economic innovation ('innovation') is the principal driver of improvements in Total Factor Productivity, the main engine of growth and prosperity in mature economies. It is also critical for achieving the green transition.

Innovation encompasses new and improved production processes, products, services and ways of doing business. It includes radical and incremental changes, using all forms of tangible and intellectual technologies. It is important for companies of all sizes, from traditional low-tech sectors to fast high growth sectors.

The private sector is the primary investor in innovation. Investment flourishes when societies create conditions in which managers and entrepreneurs are encouraged to take risks and hence create new sources of wealth, employment and social benefit.

Governments play an important role in creating a business environment that is supportive of innovation. Specifically, they influence the **"Framework Conditions"** that shape the scale and nature of innovation within societies. These are a group of exogenous factors that form part of the overall business environment and create incentives (or obstacles) for companies to invest in innovation.

The principal Framework Conditions include:

- **Macro-Political and Economic factors** – certainty, rule of law, property rights, fiscal and monetary stability.
- **Social attitudes** – towards risk-taking, enterprise and profits, commerce, new technologies (fear or acceptance), role, purpose and nature of regulation.
- **Markets and demand** – size, nature, confidence and trust, new opportunities, demanding customers, competitive intensity, barriers to market access, use of technologies.
- **Knowledge creation and dissemination** – investment in knowledge and innovation, scale, nature and effectiveness of the 'research base', dissemination through value chains, access to technologies.
- **Skills and competencies** – availability of educated and skilled workforce, access to flexible, expert suppliers and outsourced expertise.
- **Finance** – fiscal support, scale and nature of capital markets, availability of innovation funding, levels of retained earnings.

Increasingly, policy-makers also focus on the availability of certain **advanced forms of infrastructure** that support platform technologies, such as digital information technologies.

The regulatory framework, and how societies manage risks posed by technologies to man and nature, plays a critical role in shaping Framework Conditions. Used well, regulations can reduce barriers to market access, increase consumer confidence,

[1] See *ERIF Communication 23 Better Regulation, Prosperity, Transition and Resilience – Ideas for the New Commission, 2023.*

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generate trust and facilitate and, through permitting safe use, the application of new technologies. Well-designed market access rules can also limit the diversion of critical resources into Defensive R&D and speed up time-to-market. In contrast, low quality regulations can create significant obstacles.

The **EU's Framework Conditions for innovation has major strengths**, most notably the scale of the Single Market and of the EU's scientific research base, as well as the human and financial capital of its large-scale enterprises.

It also has **major weaknesses**, some related to the incomplete state of the Single Market. **(1)** Fiscal powers, an important source of incentives, lie outside the competencies of the EU. **(2)** The EU is increasingly risk averse and suspicious of commercial society. **(3)** Regulation is increasingly used as a prescriptive tool to attempt to direct economic activity rather than to enable incentives and the functioning of markets. **(4)** Expenditure on R&D is significantly lower than in competing economies. **(5)** The EU's capital markets lack scale, depth and sophistication. **(6)** Development of human capital, one of the major critical inputs, remains the responsibility of Member States. **(7)** Finally, the EU's regulatory framework poses major challenges for incentives to innovate.

ISSUES OF CONCERN

The EU is aware of some of the strengths and weaknesses of the Framework Conditions for innovation, and of the importance of fostering innovation for achieving its socio-economic goals. It has, for example, taken a series of policy initiatives implementing Art.173 TFEU, within the flagship Innovation Union initiative. Dedicated institutes and programmes have been created to foster private sector R&D spending and to direct Horizon Europe expenditure (such as EIT, EIC and other supporting measures), along with formal bodies to support decision-making processes (such as RISE, ESIR). A series of policy instruments have been supported including the Innovation Principle, Innovation Deals and Better Regulation Toolkits numbers 20 and 23.

The New European Innovation Agenda repositioned the EU's efforts in the context of the post COVID-19 recovery, the European Green Deal and the conflict in Ukraine. Within the RFF framework, it seeks to leverage access to finance, encourage regulatory experimentation ('sandboxes'), promote regional eco-systems and develop human capital. These initiatives were relaunched in the Green Deal Industrial Plan of 2023. Since 2021, the EU has also pursued the Digital Decade policy.

Despite all of these initiatives and their many predecessors, public policy interventions have failed to stimulate a significant resurgence in investment in innovation in the EU.

Indeed, the EU has experienced steady erosion in innovation performance over more than three decades, by comparison with other major trading blocs. The reasons include:

- Lower economic and productivity growth;
- Relative failure to adopt or diffuse at scale new technologies;
- Limited growth of new sectors and major new enterprises;
- Relative lack of entrepreneurship; and
- Lower levels of investment and significantly less expenditure on innovation and R&D.

In overall terms, the progressive weakening of the EU's innovation performance poses a major threat to long-run prosperity and to achieving the green transition.

In part, this is due to structural weaknesses in the EU's overall policy approach. It lacks coherence and consistency over time. It does not fully take into account the strengths and weaknesses of the EU's economy. It pays inadequate regard to the importance of large companies as investors in innovation, and places insufficient emphasis on supporting investments for incremental innovation.

One of the most important failings of the EU's innovation policy is, however, that it does not recognise fully or systematically the impact of the regulatory framework, including implementation mechanisms, on shaping incentives to invest in innovation.

EXISTING REGULATORY CHALLENGES

The overall impact of the EU's regulatory framework on investment in innovation is complex.

In several instances, regulation has strengthened incentives. High quality, excellent and impartial scientific assessments of safety by the European Commission's Scientific Committee on Consumer Safety (SCCS) have created consumer confidence and trust for the detergents, household care, personal care and cosmetics sectors, helping to strengthen market demand and, by focusing on safe use based on likelihood of harm, retained access to critical technologies. Similarly, investments and reforms in the approval processes for human and veterinary medicines have helped create incentives to invest in small markets (through the provisions of the Orphan Drug policy, for example) and to bring new products to market more rapidly. The regulation of nanotechnology, based on the safety of specific applications, rather than stigmatising the technology itself, has helped underpin the application of this important platform technology.

On the other hand, there remain major areas where improvement is necessary to overcome shortcomings in the regulatory framework. Particularly problematic areas include: (1) The widespread focus on intrinsic properties, precaution and social concern rather, than likelihood of harm based on

accepted standards of scientific integrity to justify regulatory interventions; **(2)** The disproportionate nature of risk mitigation measures, failing to consider risk-benefit, risk-risk and other dynamic impacts; **(3)** The adoption of technology-specific risk regulations, rather than focusing on the safety of applications; **(4)** The cumulative growth in regulatory requirements, diverting resources; and, **(5)** Slow, uncertain and unpredictable implementation processes.

Significant negative impacts on the Framework Conditions result from these shortcomings:

- **Loss of markets or technologies** due to restrictions, limiting the scale of demand and opportunities to add value, create new markets and satisfy customers.
- **Stigmatisation of technologies**, reducing consumer acceptance and raising barriers to investment.
- **Extended time-to-market**, increasing the capitalised cost of development, limiting the attractiveness of small markets and reducing competitive intensity
- **Loss of access to ideas** generated by upstream technologies, due to limitations on the use of technologies, particularly throughout value chains.
- **Diversion of resources** due to the high level of Defensive R&D and disproportionate restrictions, limiting the availability of capital for new ideas, undermining the dynamism of SMEs and creating incentives to retain existing technologies.

ERIF research suggests that the new approach to risk management being introduced by the European Commission (Novel Regulatory Philosophies), if adopted without reform, will create systemic uncertainty and further weaken incentives to innovate, by eroding property rights and undermining the rule of law. In turn, this will make it more difficult for investors to justify the allocation of capital to the EU.

NOVEL REGULATORY PHILOSOPHIES

Technological evolution is central to the process of achieving greater economic competitiveness and hence delivering the EU's ambitious socio-economic objectives. There are complex links between the regulatory framework and incentives to innovate, allocate capital, operate efficiently or adjust to new opportunities. Research by ERIF over more than twenty-five years has identified many of these links. (See *ERF Monograph Fostering Innovation: Better Management of Risk 2015*; *ERF Highlight Note 07 Risk Regulation and Innovation 2016*; and *ERIF Highlights Note 18 Allocation of Capital, Better Regulation and the Delivery of the Green Deal 2022*.)

The ERIF Novel Regulatory Philosophies study (NRP), completed in 2023, builds on this work and highlights new, major concerns. Based on an extensive research programme, including more than 150 depth interviews, it examined the evolution in the way in which the EU manages risk and hence the development and application of technologies. (See *ERIF Monograph Novel Regulatory Philosophies in the European Union: Directions, Implications and the Role of Better Regulation 2023*.)

The NRP study revealed a major shift in the management of risk, away from likelihood of harm, safety and safe use grounded in expert understanding of exposures and mitigated by proportionate measures. A new, novel, and largely untested approach is instead emerging across many policy domains, based on intrinsic properties, precaution, widespread restrictions, unscientific grouping and new tests of market access, specifically essentiality, non-toxic persistence and sustainability.

Looked at in greater detail, this new approach (Novel Regulatory Philosophies) has a number of defined characteristics. These include:

- **Limited focus on the core principles of Better Regulation**, including evidence-based decision-making and impact assessment. Restrictions are proposed even though there is no adequate and specific evidence underpinning them, with weak intervention logic and an inadequate assessment of costs and benefits.
- **New ways of assessing and managing potential harms**, particularly precaution, intrinsic properties, groupings, non-toxic criteria, perceived risk and social concern. Toxicological and associated scientific knowledge is marginalised and existing vertical and expert risk assessment is lost, thereby undermining scientific integrity.
- **Use of widespread restrictions and bans** on uses of substances and technologies based on intrinsic properties, often with economy-wide impacts, with use in specific applications permitted through time-limited derogations and after satisfying subjective tests of social betterment.
- **New subjective, non-toxic and social criteria, most notably essentiality, as primary tests of market access.** Safety and safe use of technologies, based on likelihood of harm, are secondary considerations.
- **Interventions focus on prescription, inputs and processes** rather than outcomes and incentives. Regulation seeks to drive technological development rather than ensuring safety, facilitating safe use and enabling innovation.

These radical changes to the way in which the EU manages the development and dissemination of technologies are being implemented without a full or widespread debate.

Moreover, this new approach to risk management (NRPs) is largely untested and hence the claimed benefits remain highly uncertain and are not supported by robust evidence of causality or empirical experience. In contrast, the costs are

expected to be significant and include resource diversion (away from safer and more sustainable activities), loss of critical technologies, major damage to SMEs and complex value chains, reduced economic dynamism, and greater obstacles to the allocation of capital.

Moreover, this new approach to risk management (NRPs) is largely untested and hence the claimed benefits remain highly uncertain and are not supported by robust evidence of causality or empirical experience.

Adoption by the EU of NRPs for the management of risk will also have significant negative impacts on incentives to invest in innovation in the EU.

INNOVATION AND NOVEL REGULATORY PHILOSOPHIES

Delivering the green transition, as well as making the EU more attractive for industrial activity, will rely heavily on policy-makers successfully shaping framework conditions to create powerful incentives to invest in innovative technologies, operating processes, products and services. **The proposed novel risk management approach is likely to create a series of obstacles that could significantly diminish incentives to invest in innovation in the EU.** These potential obstacles include:

- **Demand conditions, the most important dimension of framework conditions, will be significantly weakened** – erosion of support for scientific integrity, the use of intrinsic properties and consequential widespread bans, and the implementation of new forms of stigmatisation for managing risk will, taken together, undermine trust in existing regulatory bodies and erode consumer confidence.
- **The increased inability to capture and protect the benefits of investment is potentially a major obstacle to investment** – weakening of property rights, due to reduced confidentiality protections for market-sensitive data, the use of derogations rather than legal compliance, and the loss of business value from substances or products that are safe to use.
- **'Competitive intensity', a major driver of innovative activity in open societies, will be undermined**[2] – widespread application of derogations, the implementation of essentiality as a test of market access, and the negative impact of novel philosophies on the eco-system of SMEs, will erode market dynamism, provide incentives for rent-seeking and challenge the norms of commercial societies.
- **Additional barriers to bringing new products and technologies to market will be created** – application of mandatory sustainability policies that restrict inputs, remove the concept of safe use, lack technology neutrality and favour inputs over outcomes, will ossify technological development, placing limits on imagination and the development of new ideas.
- **Increased development costs and slower 'time-to-market' will create barriers to market access in the EU** – implementation of new, novel regulatory requirements (including multiple non-toxic criteria for market access, loss of scientific integrity and safe use, Mixture Adjustment Factors and new hazard classes), as well as the extensive testing requirements needed to meet existing standards of safety, will impose major additional costs on product development programmes, as well as creating regulatory unpredictability.
- **Access to capital needed for innovation will be reduced** – diversion of resources into Defensive R&D and reformulation along with precautionary limits on emissions and exposures, will reduce the availability of capital for investment in innovation.
- **Access to ideas, a critical input for innovation, will be reduced** – loss of upstream technologies, due to bans and restrictions or the cost of Defensive R&D, will reduce access to ideas and well-understood technological pathways for downstream industries.

Action is needed to exploit the EU's Better Regulation tools and policies to examine and reform the existing regulatory failings that undermine the framework conditions for innovation, and to develop ideas for limiting the negative impacts of the new approach to risk management.

BETTER REGULATION AND INNOVATION – REFORMS

Innovation is the most important contributor to prosperity. Investment in innovation increases productivity and leads to the development to those technologies that help meet the socio-economic goals of the EU, including the transition to a greener economy. These reforms focus on adopting firmer political commitments and enhanced policies, based on incentives, the Innovation Principle and the safe use concept.

- The Council of the European Union should renew its formal commitment and reiterate its Conclusions calling for the **application of a policy for the promotion and management of technologies, including the Innovation Principle, which will strengthen competitiveness, create incentives for innovation and justify allocation of capital**.
- The European Commission should, in the form of a Commission Decision, establish a **formal policy for Technology Development and Management**. This should include a commitment to greater application

[2] Competitive intensity is the capacity of firms in a given market to exert pressure on each other. As such, it is a critical determinant of incentives for private firms to invest in innovation or to improve operating efficiency.

of the Innovation Principle.[3] The policy should establish a set of principles to ensure coherence of all interventions that directly, or indirectly, influence the development and use of technologies, including management of risks.

This policy should be based on a set of principles that emphasise the centrality of safe use and safety based on likelihood of harm, certainty and predictability of property rights, outcomes-driven government action, and technology neutrality.

These principles should also emphasise the important role played by framework conditions, incentives and market mechanisms (including investment economics considerations and use of standards, guidance or self-regulation), of 'Safer and More Sustainable' approaches, and of technological feasibility tests.

- The European Commission should establish, in line with Better Regulation principles and guidelines, a comprehensive programme of review of existing legislation and associated implementing mechanisms, to **assess the positive and negative impacts of regulation on the EU's Framework Conditions for Innovation**, and to identify specific reforms to reduce obstacles.
- The European Commission should **promote regular benchmarking of the time and cost of product approval processes** (encompassing testing and approval for new and existing technologies and additional MS requirements and processes) and draw conclusions and make recommendations for structural improvements. Reports should be published and made available to all EU institutions.
- The European Commission should **carry out a major horizontal evaluation of the impacts of risk management laws on innovation**. This should include working with stakeholders to highlight the scale, nature and impacts of **Defensive R&D**.

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[3] See *ERF Policy Note 23 Innovation and the Management of Risk 2013*; *ERF Communication 12 Innovation Principle – Stimulating Economic Recovery 2013*; and *ERF Monograph Fostering Innovation: Better Management of Risk 2015*.