Allocation of Capital, Novel Regulatory Philosophies and Better Regulation

Highlights Note 24

- **This Highlights Note forms part of the ERIF contribution to the new Commission's Better Regulation Agenda.[1] It focuses on the allocation of capital and its importance for the delivery of the EU's ambitious socio-economic goals.**
- **Existing failings of the EU's regulatory framework make it more difficult to justify the allocation of capital to the EU. Adoption by the EU of new ways of managing risk and technology (Novel Regulatory Philosophies) are likely to exacerbate these problems because they will create systemic uncertainty and hence strategic risk.**

BACKGROUND

If the ambitious socio-economic goals of prosperity, resilience and transition are to be achieved, then the private sector will need to make investments in the EU significantly in excess of the quantity of capital required to maintain existing productive capacity. "Business as usual" is not enough.

New capital, on an enormous scale, will be required for investment in innovation in operating technologies, materials, products and services, as well as in new process and production facilities and in digital infrastructure. Major investments will also be required to bridge the gap between existing technologies and those needed to deliver the green transition, many of which do not yet exist or remain a considerable distance from viable commercial scale.

Public funding and investment will play an important role. However, sustained large-scale private sector investment will be needed to overcome public sector capacity constraints, to close the 'investment and technology gap' and to carry the risks of increased investment, often in new technologies.

There is no shortage of capital as such but capital needs to be allocated to the EU, and its socio-economic goals, in preference to other uses, jurisdictions or returning to stakeholders (whether investors or taxpayers).

The allocation of capital process that takes place within companies determines where and when investment (in ideas, processes, products, materials et al) takes place, the type of projects that will be eligible for funding and whether or not specific projects are undertaken. (See *ERIF Highlights Note 18 Allocation of Capital, Better Regulation and the Delivery of the Green Deal 2022*.)

This 'investment' process is separate from and, in general, not influenced by financing.

Within the allocation of capital process, there are three inter-linked groups of decisions, and public policy interventions can affect them all:

- **Strategic Risks** – allocation of corporate resources recognises that there are differences in the types of risks that investments face in different regional economies. Typical areas of focus are market risks, risks to property rights (including intellectual property), legal certainty and the rule-of-law, regulatory unpredictability, lack of monetary and fiscal stability, regulatory restrictions on market access or the use of critical technologies, protection of business value, and diversion of resources away from innovation and operating efficiency.
- **Framework Conditions** – public policy and the regulatory environment play a major role in creating incentives for companies to invest, particularly in innovation. For example, framework conditions for innovation are based on three groups of factors: social attitudes, demand conditions (including scale, consumer confidence, time-to-market, market access requirements and access to technologies) and availability of critical inputs (most notably ideas,

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

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technologies, capital and the impact of diversion of resources).

- **Investment Economics** – the balance of risk and reward identified for individual investment projects determines the final allocation of capital. These assessments are generally based on widely accepted principles of corporate finance most notably: **(1)** Successful projects must meet or exceed the risk-adjusted cost of capital; **(2)** All cash flows are discounted, reflecting timing of expenditure or receipt; **(3)** The cost of capital used for investment decisions is a risk-adjusted opportunity cost set by global capital markets; and **(4)** Financing decisions are separate from investment decisions.

Delivery of the EU's socio-economic goals will happen in reality only thanks to the investment decisions made by a multitude of stakeholders in both the private and public sector.

ISSUES OF CONCERN

EU policymakers are aware of the importance of private investment for the delivery of socio-economic goals. It is estimated, for example, that additional investments of Euro170 billion to Euro 290 billion per annum in excess of funds required to sustain existing productive assets, will be required to bring about the far reaching changes envisaged by the EU's green transition.

The EU has many attractions as an investment location, including political, monetary and fiscal stability and the size and maturity of the Single Market.

To stimulate additional private sector investment and building on these structural strengths, the EU has undertaken a series of policy initiatives. These include providing loans or grants for specific forms of investment or technologies; creation of investment funds to support start-ups and other early stage ventures, providing capital when regional financial markets have systemic weaknesses; establishing standards for the provision of information to influence the behaviour of investors and corporate decision-makers, particularly investments that meet environmental, social and governance criteria; and regulation to direct corporate investment activity – in areas such as semi-conductors, batteries and raw materials.

Whilst many of these initiatives are to be welcomed, they do not fully resolve important concerns. These include:

- **There is, as yet, little evidence that the EU is succeeding in attracting the very large sums of additional private sector capital** needed to deliver its socio-economic goals. Indeed, there is evidence that levels of capital investment are stagnating and, in some sectors, declining.

- There are fears that **a process of relative deindustrialisation is taking hold** and that investors are concerned about the attractiveness of the EU for capital allocation. Recent surveys by Business Europe and the European Roundtable of Industrialists confirm this.

- Corporate decision-makers are increasingly able to **choose from a range of possible projects, many of which are outside the EU**. There are significant alternative options available to investors.

- **Investment returns continue to be set on the basis of global norms and opportunity costs.** Corporate investment behaviour is strongly influenced by the concept of fiduciary duty and hence the need for projects to achieve target returns for investors and for capital to be allocated accordingly.

- **Policy-makers do not necessarily have an informed understanding of how capital allocation decisions are actually made by the private sector.** Policy interventions are not tested for impact on capital allocation – whether from the existing regulatory framework or through the progressive adoption of Novel Regulatory Philosophies (NRPs) for the management or risk.

Finally, many important EU initiatives seek to use regulation to direct investment into specific applications or activities rather than to create incentives across a larger part of the economy.

Whilst this may be an appropriate use of regulation in certain very limited circumstances, most notably wartime or actions by the industrial-military complex, research by the OECD suggests that policy-makers should use a range of instruments to strengthen framework conditions, remove obstacles and create incentives, focusing on economy-wide measures.

Regulatory interventions are generally most effective when they 'enable' rather than pre-determine technological change.

EXISTING REGULATORY CHALLENGES

These concerns are amplified by the impact on allocation of capital decisions of the EU's regulatory framework, including the adoption of Novel Regulatory Philosophies for the management or risk.

There are a series of historic regulatory weaknesses that undermine the framework conditions for investment, making it more difficult to justify allocation of capital to the EU. This include:

- **Time-to-market** – despite improvements in some policy domains, mandatory approval processes remain slow, costly and unpredictable in terms of timeline and decision-making criteria. These shortcomings increase capitalised costs of development and reduce the availability of technologies. (See *ERIF Highlights Note 15 Time-to-Market, Innovation and Better Regulation 2021*.)

- **Regulation of new technologies** – this is inconsistent. Whilst some technologies are regulated on the basis of the safety of applications, using high quality scientific evidence, others are stigmatised through technology-based laws or the influence of social concern. This reduces the opportunity to exploit certain platform technologies, thereby weakening framework conditions. (see *ERF Monograph Fostering Innovation: Better Management of Risk 2015*; and *ERF Highlight Note 07 Risk Regulation and Innovation 2016.*)

- **Defensive R&D** – in too many cases and in excess of global norms, economic operators must divert limited resources for innovation into protecting old technologies or seeking un-measurable improvements in safety, in order to comply with EU regulation. This reduces the attractiveness of allocating capital to the EU because it limits technological evolution and hence returns. (See *ERF Highlights Note 08 Defensive R&D and Innovation 2016*.)
- **Failings of the EU's Administrative State** – the EU has established an extensive framework of mechanisms at EU-level to implement legislation. To date, the governance of these executive powers is not systematic or systematically subject to the principles and standards of good regulation and administration. In too many cases implementation decisions remain disproportionate, unpredictable, unduly precautionary or take too long or impose unjustified costs. These shortcomings undermine business value, limit the application of technologies and create systemic uncertainty. (*ERIF Monograph Risk Management and the EU's Administrative State. Implementing Law through Science, Regulation and Guidance 2019*.)

The adoption by the EU of Novel Regulatory Philosophies (NRP) for the management of risk is likely to exacerbate these existing weaknesses, primarily because of its negative impact on strategic risk.

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. Specifically:

- **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, with economy-wide impacts and continued use of specific applications based on 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 diminished incentives to innovate.

Adoption by the EU of NRPs for the management of risk will also have significant negative impacts on incentives to allocate capital to the EU.

ALLOCATION OF CAPITAL AND NOVEL REGULATORY PHILOSOPHIES

Without reform, the approach proposed by the EU for the future management of technology and materials will make it significantly more difficult to justify the allocation of capital to the EU. Most importantly, it will increase strategic risk through the creation of systemic uncertainty.

When making allocation of capital decisions, investors initially assess potential strategic risks. This assessment takes place before considering framework conditions or investment economics. One of the most important potential sources of strategic risk is systemic uncertainty. Whenever this is identified, it makes it more difficult to justify the allocation of capital to a particular jurisdiction or activity.

Adoption and implementation of the EU's NRPs for the management of risk will, unless significantly amended, create systemic uncertainty. There are a number of potential causes, including:

- **Loss of scientific integrity** in the development of policy and its implementation through legislation, regulation and guidance. (See *ERIF Highlights Note 23 Scientific Integrity, Novel Regulatory Philosophies and Better Regulation 2023*.)
- **Regulatory unpredictability** due to weaknesses in the application of the Better Regulation principles and guidance.
- **Divergence from international norms and standards**, including definitions (such as Endocrine Disrupters - EDs, and Per- and Polyflourinated Substances - PFAS), hazard classes, interpretations of hazard classification guidance, non-toxic criteria for market access, exposure limits for substances, hazard classification decisions, use of toxicological science, novel forms of scientific assessment.
- **Scale, pace and nature of legislative and regulatory change**.
- **Lack of coherence** in the design and implementation of legislative, regulatory and soft law measures.
- **Growth of administrative discretion** needed to implement the requirements of the NRPs.
- **Structural weaknesses of the EU's Administrative State** – specifically the lack of capacity and competence to deal with the scale of new regulatory requirements, combined with governance weaknesses.
- **Adoption of the 'essentiality' concept to determine market access** – leading to politicised decisions and high levels of administrative discretion, threatens norms of commercial society and of the market economy (See *ERIF Highlights Note 16 "Essentiality", Better Regulation and Management of Risk from Technologies 2021*.)
- **Loss of legal certainty and weakening of the rule of law** – with decisions likely to be based on administrative preferences rather than clear and appealable legal requirements.
- **Weakening of property rights** due to widespread use of derogations, rather than compliance with law; and
- **Loss of business value without evidence of harm** due to the use of groupings and generalised restrictions based on intrinsic properties.

Action is needed by the EU to assess the negative impact of the existing regulatory framework, using Better Regulation tools and mechanisms, and to rigorously review the potential consequences of the adoption of Novel Regulatory Philosophies for the allocation of capital to the EU.

BETTER REGULATION AND ALLOCATION OF CAPITAL – REFORMS

These reforms aim to establish a clear political commitment to strengthen institutional focus on the factors that influence private sector decisions to allocate capital. They encompass a greater focus on competitiveness. As well as engendering internal changes, such commitments will signal to investors the intention of the European Union to establish a more competitiveness-friendly business climate and to pursue technological change. The reforms also consider the urgent need to review the adoption by the EU of a new approach to managing risk and hence the development of technologies.

- The Council of the European Union should formally **require the EU institutions to strengthen the framework (and reduce obstacles) for companies to allocate capital for investment in the EU,**, targeting both globally competitive investment by large, international companies and seed investment for dynamic SMEs.
- 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**.
- The European Commission should restructure the responsibilities of Commissioners and **allocate an over-arching mandate for Competitiveness to a specific Vice-President**. The Vice-President will exercise political oversight over the development and implementation of the new Technology Management policy. The role will focus on ensuring policy coherence across all interventions, so as to ensure that business activity remains in the EU, and

that framework conditions for allocation of capital and innovation are strengthened.

- In the spirit of the Inter-Institutional Agreement on Better Law-making, the Presidents of the European Parliament, the Council of the European Ministers and the European Commission should convene an ad hoc **high-level inter-institutional review** to examine the proposed changes in the EU's legal, procedural, organisational and methodological frameworks to manage risk and the development and use of material technologies. One of the principal purposes of the review should be to launch a **wide-ranging high-level policy review** about the further evolution of the traditional model of risk management.

- The European Commission should set out a **clear policy framework for the proposed use of tests of 'essentiality' for the management of technologies.** This should ensure that its application does not create systemic uncertainty, undermine incentives to innovate, or make it more difficult to allocate capital to the EU. (See *ERIF Highlights Note 19 Innovation, essentiality and Better Regulation 2022*.)

- The European Commission should revisit and clarify in a Communication the way of which it intends to use **the Safe-and-Sustainable-by-Design (SSbD) concept** for stimulating investment in safer and more sustainable technologies, substances and products.

- The European Commission should mandate the **Scientific Advice Mechanism (SAM) to establish a high-level study group to review existing methods of identifying, assessing, characterising and classifying hazards**, with a view to identifying weaknesses and making detailed recommendations for improvements, such that the new approach is fit for purpose.

  The study group should be drawn widely and include expert, eminent scientists with relevant experience in National Scientific Academies, industry and other stakeholders. The group should engage extensively with affected groups, including carrying out open hearings.

  Finally, **the study should include a detailed assessment of the role of persistence in hazard assessments, and should make separate recommendations for a new approach that is up-to-date and fit for purpose.**

- 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 of the Innovation Principle.[2] 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.

- The European Commission should revise the **Better Regulation policy and guidelines to include a 'Capital Allocation Test'** (CAT). It should be applied to all policy and legislative proposals and implementing mechanisms.

  The objective is to assess whether proposals are likely to support investment within the EU. Measures considered more likely to dissuade investment should be reported and explained in terms of other policy objectives.

  The CAT should include consideration of such issues as impact on property rights, legal certainty, access to markets (including time-to-market and restrictions on use of technologies), access to technologies and ideas, rule of law, regulatory certainty and the extent to which financial resources are diverted into defensive R&D. It should also be applied to interventions based on novel regulatory philosophies.

- 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 performance relative to policy objectives and to identify where policy and legislation can be strengthened to support the allocation of private sector capital** to delivery of the EU's socio-economic goals.

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Richard Meads, the Rapporteur of the European Regulation and Innovation Forum (ERIF), wrote this Highlights Note. However, the views and opinions expressed in this paper do not necessarily reflect or state those of ERIF or its member

[2] 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*.