



## **EUROPEAN REGULATION AND INNOVATION FORUM – POLICY NOTE 35**

### **NOVEL REGULATORY PHILOSOPHIES IN THE EUROPEAN UNION: DIRECTIONS, IMPLICATIONS, AND THE ROLE OF BETTER REGULATION**

**November 2023**

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## EXECUTIVE SUMMARY

This Policy Note summarises the main findings, conclusions and recommendations of a ground-breaking report from the European Regulation and Innovation Forum. Based on nearly 150 interviews and an extensive research programme, the report identifies a series of major issues that are critical for the future competitiveness of the EU, and hence its capacity to become greener and more resilient.<sup>1</sup>

The report highlights the following key issues:

- **Considerable success.** Regulation based on management of risk (taking account of both intrinsic properties and the degree of exposure) has made an immense contribution to European health and environmental protection and to the prosperity, choice and the quality of life enjoyed by citizens. Europeans can be proud of this approach, and it has not failed.
- **New risk management approach.** However, the European Commission is introducing a new way of managing health and environmental protection through a series of novel regulatory philosophies. These include prohibition based on intrinsic properties alone, a test of social value ('essentiality') to allow market access, greater focus on non-toxic harms ('persistence without toxicity') and directing investment according to these approaches ('sustainable by design').
- **Public debate is needed.** These are far-reaching regulatory changes but there has been no systematic public debate on either the benefits or the consequences. The report from ERIF seeks to promote and inform such a debate.
- **Insufficient benefits analysis.** The claimed benefits of these changes are to simplify and speed up regulatory decisions and the substitution of hazardous substances and products. However, the exclusion of technologies on the basis of intrinsic properties alone, and the granting of market access based on a subjective assessment of social value, will also introduce massive new complexities and legal uncertainties.
- **Serious and wide-ranging costs.** These complexities and uncertainties are very likely to offset the claimed benefits. They will also increase the costs and risks of investment, divert resources from innovation to compliance and decrease the incentive to innovate. The overall impact will be to reduce investment and innovation in Europe, at a time when exactly the opposite is needed.
- **Better Regulation is critical.** ERIF believes that all of these challenges can be addressed in a careful and constructive way through application of the principles and practices of Better Regulation, where Europe has a strong capability and track record.

In response to these findings and in line with Better Regulation principles and practices, **we recommend (1) an immediate inter-institutional review** of the introduction of novel regulatory philosophies, **(2) strengthened governance** of the regulatory process, **(3) clear standards for the use of science** in regulatory decision-making, and **(4) a constant focus on making Europe more attractive for investment and innovation.**

**European Regulation and Innovation Forum  
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<sup>1</sup> ERIF Monograph [Novel Regulatory Philosophies: Directions, Implications and the Role of Better Regulation](#), 2023.

# 1. BACKGROUND

The EU has embraced a series of ambitious socio-economic goals. It aims to deliver greater prosperity and a more sustainable, cleaner, greener and more resilient future for its citizens. Whilst there is widespread support for the overall outcomes ('ends') being sought by the EU, achieving them will be influenced critically by the choice of policy 'means'.

Risk management policies, and the way in which they are implemented, set the rules for technology management in modern societies, determining market access, allocation of capital and the exploitation of ideas. In turn, these rules influence economic and social outcomes, including the green transition, strategic resilience and prosperity.

For many years, governments have sought to manage possible hazards and established risks by ensuring safety, facilitating 'safe use' and ensuring proper exploitation of benefits. The way in which these goals are achieved has evolved over more than a century of legislation, legal judgements, and regulatory decision-making. Its methodology presents specific, defined features that include **safety, determined on the basis of likelihood of toxic harms, as the primary criterion for intervention by the State**. Assessments of safety in specific uses and applications, derived from the best available science and undertaken by relevant and eminent experts, are the basis of regulatory decisions. Once these processes are complete, customers, rather than governments, make choices based on safe alternatives.

This traditional approach is being increasingly challenged by the progressive introduction, at EU-level, of 'Novel Regulatory Philosophies' (NRPs). Overall, these constitute a radical shift in the way in which technologies will be managed in the EU. NRPs encompass a range of new ideas that are mostly untried, untested, and often controversial. Foremost amongst these at time of writing are regulatory initiatives on intrinsic properties, essential use, persistence without toxicity, and safe and sustainable by design. Other novel regulatory initiatives are also in progress or understood to be tabled.

**However, no structured and objective public debate has informed the introduction of these novel philosophies. ERIF's research concludes that, without major reform, adoption of this new approach to the management of risk by the EU poses major challenges:**

- It will be an economy-wide approach, conflicting with established risk management laws;
- It will undermine scientific integrity, marginalising toxicology;
- It will divert resources into Defensive R&D and away from investment in more sustainable and safer technologies;
- Property rights will be diminished;
- Incentives to innovate will be weakened; and
- It will create systemic uncertainty, making it more difficult to justify allocating capital to the EU.

Overall, this new approach to risk and technologies may make it more difficult for the EU to achieve its political goals.

**In light of the nature, scale and potentially far-reaching consequences of the proposed approach, this Policy Note recommends appropriate ways forward, thereby informing the public debate about the role that Better Regulation should play in shaping the delivery of the green transition and greater strategic resilience, as well as improving competitiveness and prosperity.**

## 2. MANAGEMENT OF RISK – FROM LIKELIHOOD OF HARM TO NOVEL REGULATORY PHILOSOPHIES

### 2.1. Benefits from the Traditional Risk Management Philosophy<sup>2</sup>

Across the OECD area, ‘likelihood of harm’ is the dominant risk management philosophy. This approach to risk management takes into account intrinsic properties (‘hazards’)<sup>3</sup> and the probability of adverse effects from specific exposures, focusing on safety for humans and the environment. Assessments are carried out by eminent and relevant experts using the best available science and using widely-accepted principles and guidelines of scientific integrity. Mitigation measures, guided by expert assessments, are targeted, effective and proportionate.

Using likelihood of harm to manage risk has contributed significantly to the high levels of protection of human health and nature present throughout the OECD area, and to the level of prosperity, choice and quality of life enjoyed by citizens. Critical benefits include:

- Delivers safety for man and nature
- Facilitates safe use of technology and incentives for Innovation
- Ensures safe enjoyment of benefits
- Enables flexible and dynamic regulatory policy
- Supports effective governance – justifies use of the powers of the State
- Underpins open and commercial societies

### 2.2. The Emergence of a New Approach

Despite the significant benefits that the use of likelihood of harm to manage technologies and their risks has delivered for the EU, a new approach to risk management is being adopted. At EU-level, policy, law, regulation and its implementation are being designed to direct the development, production and use of technologies, so as to achieve a series of ambitious social objectives. These encompass protection of citizens and nature from all forms of potential ‘harm (‘toxic’ and ‘non-toxic’); alleviation of societal worries or concerns; insurance against uncertainties; greater sustainability and ecological harmony; and social betterment.<sup>4</sup>

Within this new risk management context, objectives of ‘safety’ and ‘safe use’, based on likelihood of harm, are of secondary importance, and regulation becomes an intended driver of change, through direction, command and control, rather than an enabler of innovation.

Progressively, this new approach is set to replace the use of likelihood of harm as the principal philosophy for the management of risk. This new approach has a number of distinct characteristics (Exhibit 1):

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<sup>2</sup> See ERIF Highlights Note 20 [Regulation and Management of Risk – Likelihood of Harm, Safety and Safe Use](#), 2022.

<sup>3</sup> It is important to recognise that regulation of risk based on likelihood of harm does not ignore intrinsic properties. Understanding, classifying, and characterising these properties forms the first part of the scientific assessment that also considers exposures and the probability of adverse effects. In this initial phase, assessors seek to identify the inherent properties of an agent having the potential to cause adverse effects when an organism, system or population is exposed to that agent. However, the probability of adverse effect or its impact is not identified at this point.

<sup>4</sup> See ERIF Highlights Note 21 [Novel Regulatory Philosophies - Future Directions and Implications for Risk Management](#), 2023.

## Exhibit 1

### Novel Regulatory Philosophies – Overall Characteristics

- **Limited focus on the core principles of Better Regulation**, including evidence-based decision-making, impact assessment. Restrictions are proposed although 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.

Source: ERIF

The rationale for adopting this radical new approach is complex. Proponents cite technical characteristics of the traditional approach. There are concerns about potential unregulated threats to the quality of health and the environment. There is a need, it is argued, to speed up the development of new, safer and more sustainable technologies. There are also negative attitudes towards material technologies and the private sector. In part, these concerns have been amplified by a series of controversies and failures involving the corporate sector. Finally, it is argued that by adopting a radical new way of managing technologies, the EU can restructure its economic model and set global standards for regulatory action.

There are three major ways in which these new ideas are being applied. Taken together, they form a 'typology of novel philosophies' that is intended to deliver the expected social objectives. Specifically:

- The progressive 'evolution' of the traditional model of risk management (Section 2.3.);
- The adoption of non-toxic criteria (social harms and goals) for technology management (2.4.); and
- The direct steering of investment – through direct government involvement and new mandatory criteria for private sector investment decisions (2.5.).

### 2.3. Evolution of Traditional Model of Risk Management

**In many risk domains at EU-level the traditional approach to management of harms remains important. However, the use of likelihood of harm, as the principal risk management philosophy, has been challenged at EU-level over the last twenty years.** Hazard-based laws have been adopted to regulate entire risk domains. Technologies have been stigmatised through precautionary laws, and their implementation. Scientific assessments have become more precautionary and, in some instances, of insufficient quality. Too many risk mitigation measures lack proportionality. Assessments of intrinsic properties (hazards), also face major problems, including a lack of expertise and failure to meet standards of scientific integrity, and may no longer be fit for purpose.

**As a result, a predominantly precautionary and risk averse philosophy has become more influential, focusing on social relationships with technologies rather than safety, safe use and the benefits of new ideas.** Central to this new approach is the shift away from basing risk management decisions primarily on 'Likelihood of Harm' and towards greater use of intrinsic properties. The latter approach has significant potential disadvantages, which are, moreover, insufficiently understood.

The management of risk based primarily on intrinsic properties is conceptually challenging but particularly problematic in jurisdictions where principles and practices of good regulation and administration are incomplete. Over the past two decades, the EU institutions have made significant progress by introducing wide-ranging impact assessment and public consultation requirements, along with coordination and scrutiny mechanisms. However, these advances have not yet fully addressed emerging risk management trends. There are also shortcomings in the capacities and type of expertise deployed to obtain and use regulatory science, making it difficult to achieve consistent, high-quality decision-making. Finally, there are significant structural weaknesses in the institutional and legal mechanisms used by the EU to implement risk management decisions (through the EU's Administrative State).

Proposals set out in new policy initiatives at EU-level, including the Chemicals Strategy for Sustainability, will accelerate the on-going, long-run shift towards a radically new way of managing risk, and hence the development and use of technologies throughout the economy.

## **2.4. Non-Toxic Criteria to Determine Market Access**

The traditional model of risk management seeks to protect human health and the environment from potential toxic harms. It focuses on measurable damage, taking into account intrinsic properties, exposure and likelihood of harm. Market access for technologies depends upon meeting science-based tests of safety. At EU-level, these requirements are changing.

**New systemic tests of market access are being added that do not focus on protection from damage (toxicity).** These non-toxic tests encompass criteria for social betterment ('essentiality'), non-toxic intrinsic properties ('persistence without toxicity'), and the 'sustainability' of processes or substances used by the private sector.

### **2.4.1. Essentiality**

**Market access for applications of technologies will, in future, be increasingly determined on the basis of a test of 'essentiality'.** Using primarily intrinsic properties, groupings and widespread restrictions, entire classes of technologies may be banned, with continued use of specific applications permitted on an exceptional basis through derogations and after satisfying tests of essentiality.

**Essentiality is a subjective concept. There is no widely accepted or agreed definition that is appropriate for widespread application.** Its implementation will consequently depend upon interpretation and administrative discretion. It is, moreover, part of a wider theory of 'necessity' that justifies restrictions on market access for all new or existing products, unless it can be demonstrated that they are needed for "social betterment".

The objective is to restrict the availability and use of existing technologies and to try and direct the development of new ones. If implemented as proposed by the EU, the essential use concept will contribute to reversing the traditional process of risk management, whereby granular assessment precedes mitigation measures, and socio-economic factors are considered within risk-benefit analyses. In its place, tests of 'essentiality' will form part of the granular assessments for application-specific derogations from widespread bans and replace traditional socio-economic assessments.

Safety, based on exposure and likelihood of harm, and safe use will be secondary considerations. Critical technologies will be lost. There will be systemic uncertainty and property rights will be weakened, by replacing legal certainty and predictability with administrative discretion and derogations.

#### 2.4.2. Persistence

**Intrinsic properties of persistence, particularly those associated with toxicity, are widely recognised by scientists as a category of hazard that should be subject to public risk management.** Whilst hazardous, these properties are however desirable if adequately controlled and managed – for instance, to ensure stability, durability and resistance of materials and products. Indeed, their exploitation will be critical for achieving the EU's socio-economic objectives. For example, silicone chemistry, and its complex properties, is a critical enabler of the green transition, providing unique benefits of durability and resistance that extend the life of EVs and renewable energy systems.

Under the new approach to the management of risk, new hazard classes have been added and new concepts, such as 'mobility', established. There is also a greater philosophic emphasis on different forms of "persistence without toxicity". In addition, the scope of application of restrictions based on properties of persistence is being expanded, to encompass more inorganic materials through EU-specific revisions to globally accepted guidance.

However, these changes in hazard classes are being proposed and implemented without a rigorous review of the scientific evidence of potential harm or the rationale for intervention. No adequate assessment of benefits and costs has yet been carried out. At this stage, moreover, the new hazard classes and revised guidance are not globally harmonised.

**The further expansion of the application of non-toxic tests of market access, through the greater use of 'persistence' as a form of non-toxic hazard, may make it more difficult for the EU to exploit the properties of material technologies that are critical to achieving the goals of transition and resilience.** As part of the new approach to risk management, focused on intrinsic properties and precaution, it will undermine further the concept of safe use. It will also divert resources away from investment in substitutes, as well as creating regulatory unpredictability and hence uncertainty.

#### 2.4.3. Sustainability

**Achieving a more sustainable way of life, delivering carbon neutrality and economic circularity, and protecting the natural world, are among the most important policy objectives pursued by governments globally.** There is widespread support amongst citizens and companies for these goals. Moreover, well-designed legislation, when focused on economic systems, safe use, technological-neutrality, desired outcomes and appropriate incentives, can trigger investment and enable innovation in more sustainable products and production processes. Achieving sustainability is, however, difficult. There are, for example, competing definitions and dimensions, necessitating trade-offs and flexibility.

**Within this emerging policy context, the EU's approach is highly ambitious both in speed and in nature. It aims to achieve a complete and revolutionary economic transformation within a relatively short period of time.** It seeks to be comprehensive and to set a standard for global action. It envisages widespread change throughout the EU economy, on an enormous scale.

**The EU's approach to achieving the green transition is, however, becoming highly prescriptive.** It seeks increasingly to direct economic change, market behaviour and consumer

activity. Although the detailed 'means' by which the EU will deliver its sustainability goals ('ends') continue to evolve, a number of clear trends and challenges can be identified. Safety is defined on the basis of intrinsic properties rather than likelihood of harm. There is an apparent focus on 'inputs' rather than 'outcomes'. Requirements are being progressively integrated as mandatory criteria in regulatory interventions. There is also an increasing tendency to adopt "one-size-fits-all" analyses, requirements and criteria. Moreover, prescriptive approaches that favour the elimination of certain intrinsic properties may have the effect of limiting the use of safe materials that deliver sustainability benefits.

Based on these trends, the EU's emerging approach to delivering its sustainability goals may create a number of major problems, including unpredictability, complexity, administrative discretion, and a lack of workability. The impact of these problems may well be amplified by the interaction between the new sustainability mechanisms and other novel regulatory philosophies, and by the scale and pace of regulatory change.

## **2.5. Direct Steering of Investment – 'Upstream'**

**Novel approaches adopted by the EU to managing risk, and hence to the management of technologies, encompass a growing range of initiatives, including regulation, that are designed to direct investment by the private sector into socially desirable forms of innovation, operating processes and markets.**

**One of the most important concepts that underpins this new approach to risk and technology management is 'Safe and Sustainable by Design' (SSbD).** Its ideas are being applied increasingly by the private sector to investments in more sustainable products, sourcing, operating processes and target markets. Used well, SSbD is a powerful conceptual approach that offers the possibility of shaping earlier investments by the private sector in a wide range of safer and more sustainable technologies, substances and products. The European Commission is developing guidance for the application of SSbD, which is an important initiative for the consolidation of good practices.

However, as part of the new approach to the management of risk, the SSbD concept will interact with the other novel regulatory philosophies and is likely to be embedded in legislative and regulatory requirements. This will reshape its characteristics and create a series of additional challenges. Examples of recent proposals that reflect this evolution in the nature and use of the SSbD concept include the Eco-design Sustainable Product Regulation and the revision of the Industrial Emissions Directive.

The approach taken by the EU to implementing the SSbD concept, combined with the scale of implementation across the entire material economy, may create significant problems, unless reformed. These include systemic uncertainty, weakening of incentives to invest in innovation, regrettable substitution and risk-risk trade-offs, reduced safety and protection for man and nature, loss of SMEs, and major obstacles to the allocation of capital to the EU by global companies.



### 3. NOVEL REGULATORY PHILOSOPHIES – BENEFITS AND COSTS

#### 3.1. Access to Capital and Exploitation of Material Technologies

To deliver its ambitious socio-economic goals, the European Commission, supported by the EU co-legislators, has overseen the design and articulation of extensive policy and legislative changes. This is to be commended and is needed for the achievement of greater prosperity, the green transition and strategic resilience.

It is widely recognised that achieving these goals will depend, to a significant extent on the allocation of unprecedented amounts of capital to the EU and extensive investments in innovation. Most of this capital will be provided by the private sector and, recognising the realities of technological feasibility, most innovation will be based on the complex properties of material technologies (metals, chemicals, biology and biotechnology).

Whilst there is widespread support for the socio-economic 'ends' that the EU is pursuing, it is appropriate to appraise whether the 'means' chosen by the EU policy-makers are likely to be effective and proportionate or may prove counter-productive. New ways of managing risk are an explicit policy choice. They are a 'means' of achieving the EU's goals.

In this respect, **any assessment of the effectiveness of the novel regulatory philosophies being adopted at EU-level for the management of risk, should consider the positive and negative impacts that these are likely to have on achieving the goals of greater prosperity, the green transition and strategic resilience. This assessment should include consideration of their impact on incentives to allocate capital to the EU and to exploit the technologies of the material economy.**

#### 3.2. Assessment of Benefits

EU policy-makers argue that the implementation of the EU's new risk management approach will deliver significant benefits. Specifically:

- Improvements in the quality of health and the environmental;
- Enhanced framework conditions for investment and innovation; and
- Global competitive advantage.

**So far, however, there is little robust evidence of likely substantive benefits from the implementation of the EU's novel regulatory philosophies.** For example, many eminent scientists argue that there are no major regulatory gaps or new threats to health or the environment that cannot be managed adequately by existing risk management laws. They also argue that trends in human and environmental health indicators are not linked causally to reliable measures of exposures to unregulated technologies.

**There is, moreover, little evidence that the implementation of novel regulatory philosophies will improve the speed, quality or cost of regulatory decisions.** Such changes may only be possible if all applications of specific technologies are banned, without exception. This would ensure predictability and certainty. However, it is recognised by proponents of the new approach that this extreme scenario would lead to economic chaos and additional risk. To prevent this, the new approach envisages forms of derogation that provide temporary continuation of market access. **Taking into account the scale of proposed restrictions, the need for derogations and the desire by producers and users to protect property rights, it is likely that the quality of the regulatory process will deteriorate,**

**regulatory costs will rise, decisions will be slower and there will be systemic uncertainty. This will weaken framework conditions for innovation and make it more difficult to justify the allocation of capital to the EU.**

Additionally, assessments of the application of the Substitution Principle<sup>5</sup> suggest that using it to try and force rapid change through widespread mandatory bans and restrictions, is unlikely to create significant incentives to invest in innovation and may, instead, lead to economic disruption, use of old technologies and an increase net risk to health or the environment.

Finally and recognising a few limited exceptions, **non-EU jurisdictions are not adopting the novel regulatory philosophies for the regulation of risk and management of technologies being implemented in the EU. Specifically, they are following a more traditional approach to the management of risk and stimulation of economic transformation.**

### **3.3. Costs**

**The novel regulatory philosophies interact with each other. It is their combination that forms an integrated framework, which seeks to steer the development and use of technologies.** Research by ERIF has for the first time taken into account the cumulative effects of these novel philosophies and examined their potential negative impacts ('costs') using good regulatory principles and practices, particularly the assessment of dynamic effects and unintended consequences. It reveals the existence of a **series of major potential negative impacts:**

- Reduced protection of health and the environment;
- Loss of critical technologies needed for the green transition and strategic resilience;
- Systemic uncertainty;
- Diversion of resources away from investment in safer and more sustainable technologies;
- Reduced incentives to innovate;
- Structural damage to the eco-system of SMEs;
- Erosion of competitiveness of formulator industries; and
- Destruction of value for major industries.

**Taken together, these potential costs may well be significant, extensive and serious.** In this context, it is becoming increasingly difficult to justify the allocation of capital to the EU, beyond that needed to sustain existing productive capacity (and sometimes not even the minimum level). There may be a progressive fall off in the level of resources committed to the EU.

Finally, **at this stage and assuming that the EU's novel regulatory philosophies are implemented without significant reform, the limited potential for benefits does not appear to justify the likely costs. Indeed, without change there may well be significant negative unintended consequences, leading to regulatory failure.**

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<sup>5</sup> The Substitution Principle assumes that intrinsic properties are the best means of identifying potential threats, that safer alternatives are easily and readily available, and that, used rigorously, regulatory pressures will release innovation leading to rapid introduction of new safe and sustainable technologies processes, substances and products. Systemic bans and restrictions will create market opportunities and hence reshape framework conditions for innovation and for the allocation of capital to the EU.

## 4. CONCLUSIONS

The EU aims to create a greener and more strategically resilient economy in a relatively short period of time. Its intention is to be comprehensive and revolutionary, and to establish a standard for the rest of the world to follow.

To achieve these socio-economic ‘ends’, EU policy-makers have chosen radical and equally ambitious ‘means’. Central to these is the proposed adoption of novel regulatory philosophies for the management of risk and hence the development and use of material technologies throughout the European economy. **This new approach to the management of risk is, however, controversial, untested and potentially high risk. When its positive and negative potential impacts are examined in detail, it is likely that the ‘means’ may frustrate the achievement of the ‘ends’, leading not only to a major missed opportunity to achieve fundamental change but also, in light of the significance of the potential costs, to possible regulatory failure.**

In part, this situation is the result of evident failings in the way in which novel regulatory philosophies have been developed and implemented. Underlying these failings are, however, three more complex factors:

- **Better Regulation principles and tools have not been fully utilised;**
- **There has been insufficient pro-active involvement and investment by parts of the business community in supporting the shift in social and political objectives; and**
- **The new approach has emerged without a major public debate or societal consensus.**

**Ultimately, prosperity is at stake.** This must be maintained to counter threats from authoritarian regimes, crises in living costs and energy availability. To protect prosperity, the need is for effective transition<sup>6</sup>; proportionality must guide all interventions; policies must focus on incentives and outcomes; and the EU must work with the existing material economy and its technologies.

The EU institutions have the capability to meet this challenge, not least if they capitalise on the extensive and largely successful Better Regulation agenda. Major reforms are nonetheless needed to avoid the potential negative outcomes and indeed to seize the opportunity offered by the green transition, to radically develop the EU’s economy and to make it more sustainable and strategically resilient. This opportunity must not be missed.

## 5. RECOMMENDATIONS<sup>7</sup>

The reforms set out in this Policy Note are designed to achieve the EU’s political goals and avoid regulatory failure. They focus on five core themes:

- Immediately address the negative consequences of current initiatives;
- Strengthen governance of the regulatory process;
- Reinforce confidence in scientific integrity in decision-making;

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<sup>6</sup> Sustainability policies based on the concept of ‘transition’ recognise that moving to a more sustainable economic model takes time, recognise technological feasibility, embrace incremental and radical change and sustain and build on existing economic activities and structures. In contrast, policies designed on the basis of radical ‘transformation’ focus on revolutionary changes, remove existing technologies and seek to rapidly replace existing economic structures and processes.

<sup>7</sup> The ERIF Monograph [Novel Regulatory Philosophies: Directions, Implications and the Role of Better Regulation](#), 2023, identifies 25 reforms. This Policy Note only considers those reforms to which priority should be given.

- Strengthen conditions for the allocation of capital; and
- Build trust, knowledge and understanding of the role of investment.

All of the reforms are important. If implemented, they will help reshape behaviours within complex institutions.

- 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 of the design, application and consequences of the novel regulatory philosophies, before** examining proposed further changes in the EU's legal, procedural, organisational and methodological frameworks for the management of risk and the development and use of material technologies.
- The Council of European Ministers should adopt dedicated Conclusions calling for a **more robust and systematic application of the Proportionality Principle**.
- The EU Legislature should, building on the work of the European Parliament, develop and adopt a comprehensive **Law of Administrative Procedures**.
- The European Commission should adopt a Commission Decision establishing a new **group of Senior Economic Advisors**, to support the process of evaluating the potential impacts of proposed interventions.
- The Council of EU Ministers should adopt dedicated Conclusions calling for the application of **common principles, standards and guidance for Scientific Integrity in regulatory decision-making**.
- The European Commission should adopt a Commission Decision establishing a new **Office for Scientific Standards in Regulatory Decision-Making**.
- The European Commission should adopt a Commission Decision establishing a **new Independent Appeals Board for Scientific Assessments**.
- The European Commission should adopt a Commission Decision establishing a new **network of standing independent scientific committees**.
- 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 **allocate an over-arching mandate for Competitiveness to a specific Vice-President**.
- Companies and Trade Associations should commit to **investing in the further development of regulatory science** and robust and comprehensive socio-economic analyses (SEAs), and they should actively engage in **fostering dialogue and strengthening communication** with various stakeholders.

## European Regulation and Innovation Forum November 2023

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

## European Regulation and Innovation Forum

The European Regulation and Innovation Forum (ERIF) is an expert-led and not-for-profit think tank with the aim of promoting high quality decision-making by the EU institutions through Better Regulation. The ERIF was known as the European Risk Forum until January 2021.

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 governance, decision-making structures, tools, and processes; the risks and benefits of new and emerging technologies, and of lifestyle choices; obstacles and incentives for innovation, including the regulatory framework; and, the importance of high quality scientific evidence for better regulation. This approach is highly relevant at present, as the EU recovers from the COVID-19 pandemic and undertakes an effective and proportionate transition to the new economic and societal models pursued by the European Green Deal.

Better Regulation is one of the pre-conditions for delivering these goals. It seeks to strengthen consent to law-making and to the actions of the State needed to implement legal requirements. Accordingly, laws and regulations should be:

- Necessary, effective, and proportionate (resting on a rigorous definition of the policy objectives, as well as a clear and comprehensive description and assessment of problems and their underlying causes);
- Based on credible evidence, particularly science, that supports the use of the powers of the State;
- Informed by a robust and transparent understanding of costs and benefits, particularly dynamic impacts such as risk-risk trade-offs;
- Demonstrate that benefits justify costs;
- Developed using transparent and participatory decision-making processes; and,
- Reviewable over time and subject to appeals and redress mechanisms

High quality decision-making, notably risk regulation, 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, costs, benefits, and legitimacy of different policy options (risk management).

Achieving these goals is 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.

These principles and requirements form part of the approach to regulatory decision-making set out by the OECD since 1995. The approach to risk regulation promoted by the WTO also makes explicit reference to these principles and practices.

The ERIF is supported principally by the private sector. The ERIF 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 ERIF's work.

The Forum works with all EU institutions to promote ideas and debate. Original research is produced and is made widely available. 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. The ERIF directly engages in EU regulatory reform debates through targeted lunches and roundtables. The Forum also regularly contributes to public consultations launched by the EU institutions. A key feature of the ERIF's approach is its emphasis on expert-to-expert dialogue to share views and learn from good practice.

For more information visit [www.eriforum.eu](http://www.eriforum.eu) or contact [info@eriforum.eu](mailto:info@eriforum.eu).

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