European Regulation and Innovation Forum

Novel Regulatory Philosophies in the European Union: Directions, Implications, and the Role of Better Regulation

July 2023

ERIF

European Regulation & Innovation Forum

European Regulation & Innovation Forum
Rue de la Loi 227
1040 Brussels
Belgium

Telephone +32 2 613 28 28
Facsimile +32 2 613 28 29
email info@eriforum.eu
www.eriforum.eu

Foreword

This ground-breaking report from the European Regulation and Innovation Forum (ERIF) 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.

1. 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.

2. Europeans can be proud of this approach, and it has not failed.

3. 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').

4. 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.

5. 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.

6. 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.

7. 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.

8. In line with Better Regulation principles and practices, we recommend an immediate inter-institutional review of the introduction of novel regulatory philosophies, strengthened governance of the regulatory process, clear standards for the use of science in regulatory decision-making, and a constant focus on making Europe more attractive for investment and innovation.

9. With such an approach we are confident that European health and environmental protection, prosperity, choice and the quality of life can be advanced together to the benefit of all citizens.

The report and its findings are timely and insightful, an important contribution to Better Regulation and the role it can play in advancing these shared objectives.

I commend it to you.

Howard Chase
Chairman, European Regulation and Innovation Forum
July 2023

Table of Contents

Executive Summary

Background

The EU's flagship Green Deal encompasses a political vision of a more sustainable, cleaner, greener and more resilient future. Whilst there is widespread support for the overall outcomes (political '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. This is a serious gap. For the first time,

this report by ERIF identifies the characteristics of the new approach, develops a comprehensive typology of NRPs and discusses the likely impacts from their combined application. It is based on extensive stakeholder interviews and supporting desk research. Numerous practical examples of the issues raised are included in inset boxes throughout the text.

The report 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. It will create systemic uncertainty, making it more difficult to justify allocating capital to the EU. It may also 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 report recommends appropriate ways forward, thereby informing the public debate about the role that Better Regulation should play in shaping the delivery of the Green Deal and greater strategic resilience.

Management of risk – from likelihood of harm to novel regulatory philosophies

Benefits from the Traditional Risk Management Philosophy

Across the OECD area, 'likelihood of harm' is the dominant risk management philosophy. This approach to risk management takes into account intrinsic properties ('hazards')[1] and the probability of adverse effects from specific exposures, focusing on safety for humans and the environment. 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

1 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.

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

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.[2]

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.

2 See ERIF Highlights Note 21 *Novel Regulatory Philosophies – Future Directions and Implications for Risk Management*, 2023.

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
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;
- The adoption of non-toxic criteria (social harms and goals) for technology management; and
- The direct steering of investment – through direct government involvement and new mandatory criteria for private sector investment decisions.

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.

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.

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.

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 political objectives. For example, silicone chemistry, and its complex properties, is a critical enabler of the Green Deal, 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.

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, set out in the Green Deal, 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.

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.

Novel regulatory philosophies – benefits and costs

Access to Capital and Exploitation of Material Technologies

The European Green Deal is the most ambitious policy programme of the European Union in a generation, leading towards a "greener", more prosperous, more sustainable and more inclusive future. More than a new strategy for growth, it seeks to deliver a social and economic revolution.

The European Commission, supported by the EU co-legislators, has overseen the design and articulation of the Green Deal, demonstrating an exceptional and pioneering political commitment to comprehensively re-organise the EU-level policy and decision-making process. This is to be commended and is needed for the achievement of the two overarching policy goals – **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 political '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 political 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 twin goals of the green transition and greater 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.**

This report carries out such an assessment in a comprehensive manner. Several examples from a variety of sectors and technologies support the findings. They directly draw from ERIF's programme of in-depth interviews and literature review. The variety and scope of the activities described directly illustrates the wide-ranging and fundamental implications that the novel regulatory philosophies may have across the EU economy.

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[3] suggest that using it 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 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.

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**.

Conclusions

The EU's Green Deal is by far the most ambitious endeavour taken by political leaders in a generation. It 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 political '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[4]; 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 Deal, to radically develop the EU's economy and to make it more sustainable and strategically resilient. This opportunity must not be missed.

Recommendations

This monograph identifies 25 reforms. They 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;
- 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. However, **priority should be given to the following changes:**

- 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**

4 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.

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
July 2023

1. Introduction

1.1. Background

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.

The EU's flagship Green Deal encompasses a political vision of a more sustainable, cleaner, greener and more resilient future. 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 'means'.

One of the most important choices that the EU must make, as it seeks to deliver the green transition and strategic resilience, is how to manage the risks posed by the use of existing and emerging material technologies. Physical material technologies, such as metals, chemicals, biology and biotechnology, are the foundations on which our prosperity and way of life are based. Exploitation of these technologies, and their complex properties, will be critical to delivering the transition to a low carbon, greener economy and protecting our environment, as well as strengthening strategic resilience.

However, no physical material, substance or product can be absolutely safe. All pose potential threats of harm to man or nature, depending on usage and exposure. Governments have sought to manage possible risks by **ensuring safety, whilst facilitating 'safe use' and ensuring safe use 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. It now presents specific, defined features. These include **safety, determined on the basis of likelihood of toxic harms, as the primary criterion for intervention by the State**, and assessments of safety in specific uses and applications, derived from the best available science and undertaken by relevant and eminent experts. 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). These encompass a range of new ideas that are mostly untried, untested, and often controversial. Specifically:

- **New subjective and social criteria**, most notably 'essentiality' as alternatives to safety as the primary test for market access (similar ideas are also emerging for tests of 'sustainability');

- **New ways of assessing and managing potential harms** – including **intrinsic properties, grouped assessments, non-toxic harms, and social concerns;**

- **Widespread bans and restrictions** on the use of substances and technologies – economy-wide impacts, with continued use of technologies permitted on the basis of **temporary authorisations, exemptions or derogations** and after satisfying **subjective tests of social betterment**, such as 'essentiality'; and

- **Upstream policies to direct innovation or production processes** – including "safe-and-sustainable-by-design", "benign-by-design" or conditions for operating permits.

The proponents of this approach argue that the EU will be better able to achieve the ideals of a new way of living, producing, and consuming. The novel approach is designed to be revolutionary – and to set the standard for global regulatory action.

However, no structured and objective public debate has informed the introduction of these novel philosophies. In light of the nature, scale and potentially far-reaching consequences of the proposed approach, this is a serious gap.

1.2. Objectives and Scope

This Monograph by the European Regulation and Innovation Forum (ERIF) highlights and examines, for the first time in a structured and consolidated manner, the proposed

adoption by the EU of a radically new way of managing risk and hence the development and availability of technologies.

The Monograph assesses, from a good governance perspective, the nature and rationale behind these emerging novel regulatory philosophies (NRPs). It seeks to raise awareness of the nature, direction, scale and potentially far-reaching impacts of these NRPs and to promote a wider debate amongst EU and national opinion-formers, decision-makers, and other stakeholders. Finally, it aims to identify tangible ways of using the EU's Better Regulation agenda to provide greater understanding of these new ideas, such that regulatory failure can be avoided, and the wider goals of the EU, particularly prosperity, strategic resilience and delivery of the Green Deal, can be achieved.

The insights and ideas set out in this Monograph are an integral part of ERIF's work on Better Regulation, the interaction between regulation and innovation, the role of scientific evidence in decision-making and the management of risk.

Reflecting the wider goals of ERIF, this Monograph focuses on the public management of risks to human health, public safety and the environment posed by the development and use of physical material technologies (such as metals, biology, chemicals and biotechnology). Exploitation of these technologies, and their complex properties, will be critical to delivering the transition to a low carbon, greener economy, protecting the environment and strengthening strategic resilience.

1.3. Methodology

The findings, conclusions and recommendations set out in this Monograph are the result of a six-month programme of research carried out by an ERIF project team that commenced in October 2022.

The programme included almost 150 confidential, in-depth interviews with officials from the European Commission and EU Member States, experts from the OECD and other international organisations, legal scholars and academics from the EU and the United States, eminent scientists, and experts from companies and business organisations from a wide range of sectors. Interviews covered most parts of the EU's material economy, encompassing large companies, SMEs, downstream and upstream producers, suppliers to

business-to-business and business-to-consumer markets, global companies and experts with international and EU responsibilities.

A desk research exercise was also carried out. It reviewed academic literature as well as policy documents and guidance from the EU institutions, international organisations and national governments in the OECD area.

The interview programme was complemented by a series of webinars and policy lunches organised by ERIF. These examined a range of relevant themes including the Essential Use Concept, the Precautionary Principle, Scientific Integrity and Hazard Classification, Allocation of Capital, the EU's Chemicals Sustainability Strategy and Safe and Sustainable by Design.

Alongside these sources, the project team reviewed the findings of research carried out by ERIF over the last decade. During this period, ERIF has published research papers (ERIF Monographs, Policy Notes and Highlights Notes) and communications that have examined a series of issues of relevance to the adoption by the EU of novel philosophies for the management of technologies. The findings developed in these papers have benefitted from the insights of eminent scientists and legal scholars, and from experts in academia, the EU institutions and the business community.[5]

1.4. Report Structure

The first part of the Monograph (**Section 2**) examines the traditional approach to the management of risk, and hence the use and development of technologies. It identifies the principles on which the likelihood of harm philosophy of risk management is based, along with the major social, economic and governance benefits that societies gain from its widespread application. It concludes by recognising that the use of the likelihood of harm at EU-level is being progressively eroded through the adoption of NRPs for the management of risk. The section highlights the overall characteristics of this new approach and assesses the possible rationale for its adoption.

5 All ERIF's publications can be freely retrieved from the think tank's website at https://www.eriforum.eu/publications.html.

Section 3 examines the EU's emerging Novel Regulatory Philosophies for the management of risk. It highlights how the new approach is being implemented through the adoption of a series of novel, and to a great extent untested, regulatory philosophies. It comments on the three principal ways in which the novel approach to risk management is taking shape:

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

Section 4 considers the relationships between the EU's political goals and risk management policy. It highlights the need to understand the potential impact of adopting novel risk management philosophies on the decision-making processes of the private sector. These determine how capital is allocated and how resources are invested in developing and using material technologies.

Section 5 assesses the potential benefits and costs of applying the NRPs to the management of risk at EU-level and hence the development and use of technologies. It examines critically the potential benefits. It also identifies possible costs, including issues of potential regulatory failure.

The final parts of the Monograph set out conclusions (**Section 6**) and comprehensive recommendations for reform (**Section 7**).

2. Regulation and management of risk – likelihood of harm, safety and safe use

This section examines likelihood of harm, the traditional approach used by OECD governments for managing risks. It identifies the principles on which it is based (section 2.1.) and its benefits (2.2.). Its continued application at EU-level is, however, being undermined by the application of NRPs for the management of risk. The overall characteristics of this new approach and the possible rationale for its adoption are highlighted (2.3.).

2.1. Likelihood of Harm – Origins and Principles

Across the OECD area, 'likelihood of harm' is the dominant risk management philosophy. This approach takes into account intrinsic properties ('hazards')[6] and the probability of adverse effects from specific exposures, focusing on safety for humans and the environment.

Its origins date back over more than two centuries and lie in the emerging role of the State as a public risk manager, protecting citizens and workers against involuntary exposures to toxic harms.

Likelihood of harm, as a regulatory philosophy, is based on a series of principles[7] (**Exhibit 1**).

Taken together, these principles have shaped decision-making processes that satisfy the four primary requirements of Better Regulation:

- Decisions are based on evidence;
- Consequences of interventions are recognised and understood;

6 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 and should be considered in a subsequent assessment before deciding on risk management measures.

7 See ERIF Highlights Note 20 *Regulation and the Management of Risk – Likelihood of Harm, Safety and Safe Use,* 2022.

- Mitigation measures are proportionate; and
- There is process legitimacy through predictability, certainty, the rule of law and transparency.

EXHIBIT 1
RISK MANAGEMENT BASED ON LIKELIHOOD OF HARM – CORE PRINCIPLES

- **Safety** – this is the primary objective of risk management policy. In most cases, there are no other objectives, therefore avoiding the possibility of undesirable regulatory trade-offs, unpredictability, and failure. 'Safety' focuses on identifying and mitigating specific harms for a particular subset or grouping, leading to measurable improvements in outcomes;
- **Safe use of technologies** – measures recognise the benefits of technologies and accept the importance, for social and economic progress, of making risk-benefit assessments. It is also accepted that 'controlled toxicity' is, for certain products, critical for human safety and public health such as control of parasites;
- **Likelihood of harm based on specific exposures** – assessments are based on real world activities, exposures and applications, focusing on the probability of adverse impacts. This approach facilitates, moreover, the estimation of risk profiles, helping risk managers make transparent choices between measures to protect humans or nature, for example;
- **Toxic harms** – risk management regulations focus on mitigating harms that present a probable threat to the physical health of humans or damage to the natural world;

- **Tangible benefits for man or nature** – legislative interventions target specific toxic threats that cannot be controlled in other ways, and are justified on the basis of measurable improvements in mortality, morbidity, or environmental quality. This helps legitimate the use of the powers of the State;

- **Toxicological knowledge** – assessments of potential harm fully reflect toxicological principles, most notably they recognise that 'the dose makes the poison'. They accept that hazards and potentially harmful intrinsic properties are always likely to be present when developing, producing or using technologies, but that the insights from toxicology and related scientific disciplines including pharmacology, help societies manage them safely;

- **Controlled toxicity** – the principles and insights of toxicological knowledge enable societies to use the toxic properties of materials in a highly controlled manner that reflects exposures and impacts. Controlled toxicity is critical for public health, human safety and protection of assets, and for the safe use of technologies that underpin high standards of protection and prosperity, such as chlorinated water;

- **Scientific evidence** – interventions and mitigation measures are based on the best available scientific evidence assessed by eminent scientists with relevant knowledge of specific application and exposures;

- **Separation of assessment from management of risk** – this form of decision-making process, often achieved through institutional design, reinforces transparency and accountability;

- **Proportionality** – mitigation measures are proportionate. They target the specific cause, aim to minimise distortion or cost, and seek to ensure that benefits justify costs. Such measures are rational, effective and transparent;

- **Predictability** – risk assessment and management processes focus on specific applications and exposures, follow due process standards and propose mitigation measures that aim to provide legal certainty. Moreover, basing risk management decisions on scientific evidence and proportionality, creates a high level of regulatory predictability;

- **Transparency** – the overall decision-making cycle, encompassing assessment and management, is transparent and based on science. This helps to create trust in regulators and their decisions, as well as facilitating the consent of those regulated;

- **Distributional Impacts** – measures can be assessed for their positive and negative impacts on different social groups.

Source: ERIF

When governments manage risks using 'likelihood of harm', the overall direction of technology development is determined by the choices made by customers between safe products and by competition between suppliers, using safe technologies. Governments play an important role by: (1) ensuring that substances and products are safe and risks are controlled; (2) facilitating safe use of material technologies; (3) making trade-offs explicit; (4) developing incentives to invest in socially desirable outcomes; and (5) using regulation as an 'enabler'.

2.2. Likelihood of Harm – Benefits

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. It is a fundamental part of the regulatory framework, tried, tested, evolved and effective. Critical benefits include:

- **Safety** – An expanding range of harms that pose a threat to safety have been restricted and, where necessary, banned, after taking into account exposures and advances in scientific knowledge. Interventions have been targeted, and outcomes measurable.

- **Safe Use of Technology and Incentives for Innovation** – Managing the risks posed by technologies on the basis of likelihood of harm helps create powerful incentives for innovation (**Exhibit 2**). Specifically:

  - Establishing safe use enables access to palettes of well-understood materials and the progressive evolution of technological pathways for incremental innovation;

  - Strong property rights, a pre-condition for investment, emerge from the risk management process;

  - The regulatory focus on safety and a high-quality decision-making process creates trust, strengthening consumer confidence – trust in product safety facilitates competition and acceptance of new ideas;

  - The regulatory process is predictable and proportionate, reducing uncertainty for investors in innovation;

  - Access to export markets is enhanced, because of the high quality of domestic risk management decisions; and

  - Trade frictions are reduced because risk management decisions respect the principles of WTO-based trade.

- **Safe Enjoyment of Benefits** – by permitting the safe use of technologies and facilitating innovation, risk management measures based on the likelihood of harm contribute to a greater range of consumer choice. In turn, competitive intensity between private sector companies, including highly innovative and dynamic Small and Medium-sized Enterprises (SMEs), drives additional economic activity. This results in greater prosperity.

EXHIBIT 2

LIKELIHOOD OF HARM, SAFE USE AND TECHNOLOGY DEVELOPMENT

Safe use of complex materials, based on scientific evidence, understanding of exposures and proportionate risk mitigation measures, is one of the principles of the traditional approach to the management of risk. It ensures safety, facilitates risk-benefit trade-offs and permits the exploitation of technologies critical for the green transition, strategic resilience and prosperity.

One example of the safe use concept is the exploitation of the unique properties of high temperature insulation materials. These inorganic materials, synthetic vitreous and polycrystalline wools, provide insulation and refractory properties above 1,000 degrees Celsius. They are used widely in process industries, such as ferrous and non-ferrous metal processing, furnace applications and chemical processing, where their properties enable hazardous industrial processes to function safely, protecting man and nature, and to operate at high levels of operating efficiency, maximising productivity, minimising cycle times and reducing energy consumption.

Some of these materials possess, however, potentially harmful intrinsic properties. They are classified as CMR (Carcinogenic, Mutagenic or Reprotoxic) category one hazards and pose a threat to the health of workers involved in their production and conversion, but typically this is not the case when installed and in their use phase.

Risk management based on the implementation of NRPs could lead to these materials being banned or only used on the basis of a derogation, a weak and temporary form of property right based on administrative discretion. In this situation, it would be difficult to justify allocation of capital to invest in innovation or new applications, leading, over time, to a progressive diminution in the relative efficiency of user industries and the retention of older process technologies.

Historically, however, the risks posed by these critical materials have been managed on the basis of likelihood of harm. Workforce exposures have been mitigated through exposure limits, protective equipment and a long-term health-monitoring programme. Producers have invested in a multi-decade product stewardship programme that has demonstrated safe use, as well as monitoring potential long-term health impacts. Its findings have shown that the risk from exposure is very limited and well managed.

US regulators have accepted these findings and developed exposure limits, recommended by industry, that reflect them. In the EU, the progressive adoption of NRPs, including unscientific groupings and focus on intrinsic properties, poses challenges to the continued availability of these complex materials.

If safe use of these materials is lost or based only on derogations, there could be significant negative consequences for safety, strategic resilience, prosperity and the green transition. These will pose problems for innovation in aerospace, where these materials provide lightweight fire resistance, and in EVs, where the properties of complex fibres are critical for preventing battery fires and for extending battery life.

Source: ERIF

- **Flexibility and Dynamism** – policy-makers have access to a flexible, yet robust, philosophy for managing the potential harms posed by the development, production, and use of technologies. Over time, this approach has accommodated, without distorting its effectiveness or undermining its principles, a number of additional characteristics including:

  - Additional risk management objectives of quality and efficacy for human and veterinary medicines and the recognition in EU law of 'Other Legitimate Factors' for determining mitigation measures for food and drink;

- Limited, science-based groupings of substances when data gaps need to be closed and the use of safety factors when assessing acceptable likelihood of harm – experience from toxicological regulatory science provides relevant insights and guidance; and

- Use of 'controlled toxicity' based on toxicological knowledge, a characteristic of some technologies that remains critical for the continued safety of humans and nature (Exhibit 3).

EXHIBIT 3
CONTROLLED TOXICITY AND SAFETY – BIOCIDES

Basing risk management on likelihood of harm, rather than intrinsic properties, enables societies to use the toxic properties of substances in a highly controlled and safe manner. The concept of 'controlled toxicity' is the result of applying the principles and insights of toxicological knowledge and it is critical for public health, human safety and the protection of assets.

The safe use of the properties of biocides provides an illustration of controlled toxicity. These complex substances protect against pests and other organisms that pose threats to human health, food, the environment and physical assets, including houses and critical infrastructure. They have three main types of application:

- Disinfectants – biocides control or destroy micro-organisms that pose threats of ill health and disease. They are widely used in human hygiene, veterinary hygiene, food processing, food preparation and drinking water;

- Preservatives – biocides prevent deterioration, extend shelf life, sustain integrity and retain initial properties. They are used to protect physical assets and within complex industrial processes. These applications also provide benefits for human health;

- Pest control – biocides repel, control or destroy pests that carry disease, contaminate food, damage buildings and undermine critical infrastructure, such as power transmission. Control of pests is critical for public health, protection of the value of assets and public safety.

At EU-level, biocides are extensively regulated. Use of active ingredients with biocidal properties requires mandatory pre-market approval. In contrast to other jurisdictions, the regulation of biocides in the EU employs hazard-based criteria, using intrinsic properties, to influence risk management, rather than solely focusing on likelihood of harm. This form of hazard-based regulation, combined with a precautionary approach to determining safety and efficacy, has contributed to a major increase in the time and cost of product development and retention. Numbers of active ingredients have fallen by 75%, sharply limiting the diversity of available solutions and increasing the risk of over-dependence and decreasing efficacy; defensive R&D consumes almost all innovation resources; and virtually no new actives have been placed on the market since 2005. New biocidal substances are needed to control the potential threats that emerge due to the development of biological resistance, for example. The progressive reduction in the means of protecting citizens and nature against biological harms threatens public health, the environment and public safety.

Controlled toxicity, through the safe use of complex substances, is also critical in other sectors, most notably crop protection, veterinary medicines and human pharmaceuticals.

Source: ERIF

- **Governance and the Use of the Powers of the State** – one of the most important benefits of the widespread use of the likelihood of harm as a regulatory philosophy, is its contribution to good governance. This philosophy of risk management, and its principles, enables regulators to justify clearly and transparently why the powers of the State to compel compliance have been employed. Its use, moreover, helps to limit the risk of regulatory failure. Interventions are based on evidence, specifically high-quality

science. It targets specific improvements in human health or environmental quality for identified groups, facilitating measurement of tangible outcomes, assessments of costs and benefits and risk-benefit trade-offs. Finally it helps to create process legitimacy.

- **Open and Commercial Societies** – the emergence of the likelihood of harm as the dominant regulatory philosophy for the management of risk is, in part, the result of the growth of open, commercial societies. It has been shaped by the norms of such societies, as well as reinforcing them. It facilitates choice and trust. It offers customers choice between safe products. It facilitates innovation. It allows markets, rather than officials, to respond to emerging needs of customers, such as greater demands for sustainability. Finally, the rule of law is strengthened. Restrictions are proportionate, targeted and based on predictable processes. There is also legal certainty and strong property rights.

Notwithstanding these benefits, the EU institutions have begun to diverge from this risk management approach. From a Better Regulation perspective, policy measures that undermine, mutate, or replace this approach, should consequently have a clear intervention logic that demonstrates why this existing approach is failing and how any new philosophy will deliver greater net benefits for man and nature.

2.3. Replacement of Likelihood of Harm at EU-level – Characteristics and Rationale of Novel Regulatory Philosophies

A new approach to risk management is being adopted at EU-level. It is progressively replacing the use of likelihood of harm as the principal regulatory philosophy for the management of risk. This new approach is radical and controversial.

Overall, the EU's new approach to the management of risk has a number of distinct characteristics (**Exhibit 4**).

EXHIBIT 4
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. However, EU policy documents and legislative proposals point to a number of important factors that seek to legitimate the adoption of NRPs to guide risk management decisions at EU level. Specifically, proponents of the new approach cite the following as important reasons for change:

- **Technical characteristics of the traditional approach** – These include the time needed to carry out assessments; the scale and quality of data required for good decisions; the level and extent of expertise required to assess exposures; and the recognition that assessments must often make expert judgements about scientific uncertainties.

Concerns about health and protection of the environment – It is argued that the existing approach is too slow, preventing the EU from delivering urgent action. The existing approach is, therefore, inappropriate for responding to health and environmental crises. In its place, the swift phasing out of all hazardous substances based on intrinsic properties and the direction of economic activity for social betterment is presented as the alternative solution.

Failure of business to speed up the development of new, safer and more sustainable technologies – More rapid restrictions, based on intrinsic properties, would, it is contended, speed up substitution towards 'safe' and 'sustainable' outcomes and trigger innovation, thereby stimulating economic growth, better health and delivery of the EU's Green Deal. An important part of the rationale for adopting this prescriptive approach is a perceived extensive failure by the private sector to respond fully to the political ambitions of the EU and to invest in the development of safer and more sustainable technologies. In the light of this, action is needed by the EU to direct investment and technology development by the private sector.

Negative attitudes towards material technologies and the private sector – there is, it is argued, a lack of public trust in the private sector and its material technologies. In part, this is due to a series of controversies and failures by the corporate sector. These concerns are amplified by deeply rooted scepticism, amongst influential social groups, about the benefits of material technologies, the profit motive, economic growth, consumer choice and the market economy.

Intellectual scepticism about the value of evidence to inform regulation – There is, amongst some opinion-formers, a post-modernist scepticism about the value of scientific evidence in rationalising decision-making, resolving the uncertainties inherent in scientific assessments and determining the likelihood of harm.

Global influence – It is also argued that by adopting a radical new way of managing technologies, the EU can restructure its economic model, stimulating innovation and growth, creating global competitive advantage and delivering safer and more sustainable prosperity.

Moral duty – There is a belief amongst decision-makers that radical action is needed because of the EU's moral duty to act as a global leader for sustainable development.

The new approach to risk management takes various forms, which can be consolidated in a specific typology of NRPs. Each part has its own nature and challenges. For the first time, work by ERIF considers them comprehensively, since all of them, taken together, are meant to contribute to delivering on the EU overarching policy objectives (see Section 4 below).

3. EU risk management – new approach and novel regulatory philosophies

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.[8]

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.

This section examines the new approach to managing risk. It highlights how the approach is being implemented through the adoption of a series of novel, and to a great extent untested, regulatory philosophies.

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 3.1.);
- The adoption of non-toxic criteria (social harms and goals) for technology management (3.2.); and
- The direct steering of investment – through direct government involvement and new mandatory criteria for private sector investment decisions (3.3.).

8 See ERIF Highlights Note 21 *Novel Regulatory Philosophies – Future Directions and Implications for Risk Management*, 2023.

3.1. Evolution of Traditional Model of Risk Management

3.1.1. Trends – Precaution and Intrinsic Properties

In many risk domains at EU-level, the traditional approach to management of harms remains important. In human pharmaceuticals, veterinary medicines, medical devices, cosmetics, detergents and some industrial chemicals, for example, decisions continue to be based primarily on likelihood of harm, thereby ensuring safety whilst also facilitating safe use.

Over the last twenty years, however, the traditional approach to risk management has been challenged at EU-level. Major changes, and some major implications, include:

- **Hazard-based laws** have been adopted to regulate entire risk domains, most notably biocides and crop protection. An underlying assumption of the hazard-based approach is that it will induce innovation and improve protection. Instead, its use has contributed to major reductions in product availability in both sectors. It has diverted resources into Defensive R&D, increased the capitalised costs of developing new technologies and created incentives to retain and defend old substances and products. There is, moreover, little evidence that the change in regulatory philosophy has stimulated investment in innovation or improved protection of human health and the environment. Indeed, the reduced availability of critical technologies is likely to have created risk-risk outcomes, leading to increased net risk.[9]

- **Technologies have been stigmatised** through precautionary laws, and their implementation, based on intrinsic properties and responding to social concern rather than science. This has led to stigmatisation of technologies, most notably of biotechnology, critical for the green transition, strategic resilience and prosperity. It makes more difficult, for example, for the EU to exploit fully the potential of gene editing and other advanced technologies, such as new materials for batteries.

9 See ERIF Highlights Note 15 *Time-to-Market, Innovation and Better Regulation,* 2021.

- There is extensive evidence across several sectors that **scientific assessments have become more precautionary** and, in some instances, of insufficient quality.[10,11] One of the causes of this is the progressive exclusion of the most eminent and relevant scientists because of their historic involvement with the commercial economy[12]. There has also been inappropriate use of the Precautionary Principle within scientific assessments.[13,14]

- **Too many risk mitigation measures lack proportionality**, failing to fully account for risk-benefit considerations and unintended consequences (including risk-risk trade-offs, stigmatisation and the diversion of resources away from investment in safer and more sustainable alternatives).[15]

- **Assessments of intrinsic properties (hazards), for example, face major problems**, including a lack of expertise, failure to meet standards of scientific integrity and may no longer be fit for purpose[16] (**Exhibit 5**).

10 Scientific assessments combine a critical evaluation of evidence (including data) with expert judgement. They are evaluations of a body of scientific or technical knowledge that typically synthesises multiple factual inputs, data, models, assumptions and best professional judgements to bridge uncertainties in the available information. Such assessments include, but are not limited to state-of-science reports; technology assessments; weight-of-evidence analyses; meta analyses; health, safety or ecological risk assessments; toxicological characterisations of substances; integrated assessment models; hazard determinations; or exposure assessments. (Source: derived from a definition used by the US Office of Management and Budget).

11 See ERF Monograph *Risk Management and the EU's Administrative State: Nature, Scale and Implications of Implementing Risk Management Law through Science, Regulation and Guidance*, 2019.

12 See ERF Monograph *Risk Management and Scientific Assessments – Understanding Conflicts of Interest and Managing Bias for Scientific Excellence and Impartiality*, 2020.

13 Developed initially as a regulatory principle for environmental protection, the Precautionary Principle permits regulatory interventions when there is an incomplete understanding of potential harm. Without effective governance, its application can become arbitrary and capricious, legitimating interventions that lack credible scientific evidence and creating systemic uncertainty. See ERF Policy Note 14 *Precaution and Regulatory Decision-Making at EU-level*, 2009; and ERIF Highlights Note 3 *Precaution and Risk Management – Modern Issues*, 2015.

14 See European Commission (2000), *Communication on the Precautionary Principle*, COM(2000) 1 final. This commitment by the Commission restricts the use of the Precautionary Principle to the justification of risk management decisions. It should not be used within the scientific assessment of risk that precedes mitigation measures. Increasingly, this requirement is insufficiently respected during the process of implementing risk management laws.

15 See ERIF Highlights Note *Proportionality Principle and the Management of Risk*, 2020.

16 For example, when considering potential harms to human health, hazard assessments should meet the following scientific criteria: (1) There has been exposure to the agent that is suspected of causing harm, in a sufficient quantity to cause symptoms – the concept of a dose-effect relationship is critical; (2) The mechanism of action of the poison should be consistent with an ability to generate the symptomatology of the affected individual(s); (3) The temporal relationship of the apparent exposure to the onset of symptoms must be consistent with the likely mode of action of compound suspected to have caused the injury; and (4) The progression of the illness believed to have been caused by the poison follows a course consistent with the injury that might be expected from the known toxicity of the compound under suspicion.

EXHIBIT 5

HAZARD ASSESSMENT – WEAKNESSES

Identification, assessment and classification of hazardous intrinsic properties is the initial step followed by regulators when developing measures to manage harms. Good hazard assessments are based on widely accepted scientific principles, as well as usage based on normal handling and use. Whilst many hazard assessments at EU-level are of high quality, too many are not. Problems include:

- Lack of expertise within scientific committees;
- Inappropriate influence of the Precautionary Principle within assessments, placing undue emphasis on poorly substantiated concerns;
- Insufficient use of data generation to fill knowledge gaps when necessary or feasible so as to reduce uncertainties and hence avoid the application of the Precautionary Principle;
- Use of non-standard test methods, species and novel toxicological theories;
- Use of data from studies that cannot be repeated;
- Failure to consider normal handling and use – detection is not hazard;
- Undue influence of discredited or poor quality studies;
- Selective use of evidence – "cherry picking";
- Over-reliance on single studies and worst case scenarios;
- Failure to comply fully with requirements to base assessments on high quality scientific studies;
- Inflexible and inappropriate application of test methods, failure to adapt to specific technologies – such as metals, metallic chemistry, silicones, coatings;
- Inadequate use of weight-of-evidence;
- Lack of consistency with underlying scientific evidence;
- Exclusion of relevant and eminent experts with experience of the commercial economy;
- Use of non-harmonised hazard classes, definitions and guidance;
- Failure to apply proportionality fully;

- Application of hazard classes that lack agreed definitions, methods of assessment, yet have a highly complex influence on human health, with potential for misinterpretation;
- Lack of full consultation with experts from producers and affected entities;
- Unscientific use of 'read across' – such as from metallic compounds to metals;
- Failure to consider natural background and essentiality for life; and
- Undue influence of political considerations.

Source: ERIF

Overall 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.[17] **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 as the basis for policy initiatives and regulatory interventions.**

Whilst in some limited instances intrinsic properties should be the primary basis for risk management measures,[18] the rationale for generalising the approach is questionable and disputed. Eminent scientists argue, for example, that the EU has one of the most complete and effective risk management frameworks for human health in the world and that there is no compelling evidence of a human health crisis within the EU.[19] Work by the OECD has also warned against a default application of the precautionary principle, arguing that this may hinder proportionate decision-making and hamper regulatory agility. There is, moreover, little systemic evidence that basing mitigation

17 See ERF Highlights Note *Precaution and Risk Management – Modern Issues*, 2015.

18 Basing specific, targeted measures on intrinsic properties is a well-accepted scientific and policy approach to managing risk and forms a complementary dimension of the likelihood of harm philosophy of regulation. Examples include potential harms when exposure conditions cannot be predicted or when no threshold for adverse effects can be identified. Interventions may also be based primarily on intrinsic properties when the toxicological hazard is acute, such that materials are deemed to be too inherently dangerous. These are, however, a limited number of circumstances.

19 See for example Bridges, J.W., et al. (2023), "Is the EU chemicals strategy for sustainability a green deal?", in *Regulatory Toxicology and Pharmacology*, Vol. 139; Barile, F.A. et al. (2021), "The EU Chemicals strategy for sustainability: In support of the BfR position", in *Archives of Toxicology*, Vol. 95; and Herzler, M. et al. (2021), "The EU chemicals strategy for sustainability questions regulatory toxicology as we know it; is it all rooted in sound scientific evidence", in *Archives of Toxicology*, Vol. 95. Senior officials from the German Federal Institute for Risk Assessment (BfR) submitted the last article.

decisions primarily on intrinsic properties stimulates widespread beneficial substitution or creates incentives to innovate.[20] Its use also raises important questions about the legitimacy with which State powers are used.

The potential disadvantages of basing risk management primarily on intrinsic properties are significant and not well understood (**Exhibit 6**).

EXHIBIT 6
INTRINSIC PROPERTIES – DISADVANTAGES

- **An intrinsic properties approach does not necessarily improve safety** – Hazard is not harm; a harmful adverse effect is present when there is a likelihood of harm due to excessive exposure. Under the intrinsic properties approach, substances are lost that provide 'controlled toxicity' when used safely and thereby protect public health, for example. It fails to recognise that 'safe' ingredients when combined together do not necessarily create 'safe' products. Its application is likely to lead to the loss of critical efficacy benefits from safe use of technologies that create safer production processes or products. Potential risk-risk outcomes due to behavioural change are not recognised. Risk-benefit trade-offs cannot be made, leading to an irreversible loss of benefits.

- **It damages incentives to innovate** – Because of the loss, without justification, of technologies that are essential for prosperity, resilience and the green transition, revenues and gross margins from well-established products that are safe to use are reduced, thereby eroding financial resources particularly for SMEs and, in addition, undermining economic dynamism. Loss of technologies also diverts resources away from existing innovation pathways without evidence of likelihood of harm.

20 See for example OECD (2010), *Risk and Regulatory Policy. Improving the Governance of Risk*, OECD Publishing; and OECD (2023), *Understanding and Applying the Precautionary Principle in the Energy Transition*, OECD Publishing.

Consumer confidence and trust are eroded due to social amplification of risk and stigmatisation by public authorities, leading to loss of markets. Trade frictions are exacerbated because global trading rules are based primarily on likelihood of harm. Public support for new technologies and risk-taking is weakened, leading instead to risk aversion and a "zero risk" culture.

- **It undermines policy integration and coherence** – The use of intrinsic properties to regulate risk is likely to make it more difficult for the EU to achieve its wider goals of delivering the Green Deal. It restricts the exploitation of material technologies that are critical to achieving the green transition and, based on the likelihood of harm, are safe to use. To a great extent this approach to managing risk is not embedded in the various EU policies, For example, the strategies outlined by the European Commission to promote industrial policy, research and innovation are not aligned with this novel approach to risk management and may be jeopardised by it[21].

- **It undermines legitimacy and governance** – There is a lack of a clear justification for the use of the powers of the State. No specific harm is identified by measures based primarily on intrinsic properties and hence the benefits of interventions cannot be assessed. The EU's commitment to evidence-based decision-making is undermined, moreover, because the science of toxicology is marginalised. It is difficult to demonstrate likely improvements in safety in advance of the implementation of measures. The rule of law is weakened because interventions are not based on comprehensive analyses of costs and benefits, thereby ensuring proportionality. Property rights are eroded because there is widespread recourse to derogations. There is a major risk of regulatory failure because protection may be reduced and significant negative unintended consequences may emerge.

Source: ERIF[22]

21 See for example European Commission (2021), Communication on Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery, COM(2021) 350 final; and European Commission (2022), Communication on A New Innovation Agenda, COM(2022) 332 final.

22 See ERF Highlights Note 2 *Hazard-Based Regulation – Acknowledging Problems*, 2015.

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).[23]

3.1.2. Recent Developments in Risk Management

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. This will affect the development and use of technologies throughout the economy.

These new proposals, along with the major changes that have occurred progressively over the last twenty years, set a clear direction for the EU's future management of risk (**Exhibit 7**):

EXHIBIT 7
FUTURE MANAGEMENT OF RISK AT EU-LEVEL – KEY TRENDS

- Management of uses and development of material technologies primarily on the basis of their intrinsic properties (rather than likelihood of harm and safe use);

23 See ERF Highlights 5 *EU Law of Administrative Procedures – Meeting the Challenge of Better Regulation*, 2015; ERF Highlights Note 6 *EU Law of Administrative Procedures – Improving Risk Management, Governance and Innovation,* 2015; and ERF Monograph *Risk Management and the EU's Administrative State: Nature, Scale and Implications of Implementing Risk Management Law through Science, Regulation and Guidance,* 2019.

- Interventions seek to avoid all harms (toxicity, as well as social worries and concerns), current uncertainties and future regrets;
- Progressive expansion of 'horizontal' risk management laws and implementation measures, at the expense of well-established and effective 'vertical' measures targeting specific sectors, exposures or economic activities – loss of world-leading safety assessments, undermining of effective risk management frameworks;
- Major expansion of the scope of risk management laws and of their implementation (new hazard classes, polymers, small volume substances, grouped restrictions or bans) – less proportionality or focus on risk-benefit;
- Much greater use of groupings of substances into 'technology families', with as yet unclear scientific justification – all members of a group would be assumed to have the same intrinsic properties;
- Use of groupings for the application of widespread mitigation measures – limited consideration of likelihood of harm or safe use of applications;
- Widespread bans, based on intrinsic properties, precede granular assessments of applications;
- Weakened property rights due to requirements to disclose confidential data critical for competitiveness, as part of a greater use of 'horizontal' scientific assessments;
- Changes in governance of independent scientific committees, eroding expertise, lessening understanding of safety and threatening quality of assessments;
- Use of arbitrary and precautionary adjustment factors within scientific assessments of new and existing substances – robust scientific evidence to support this is still lacking;
- Extensive regulatory unpredictability and greater administrative discretion due to scale and nature of interventions, weakening of scientific integrity and lack of capability and expertise of EU's Administrative State;
- Extensive use of novel risk mitigation measures including derogations, Advice of Regulatory Needs (ARNs) and stigmatisation, weakening property rights and creating uncertainty;

- Greater and more pervasive use of precaution rather than proportionality; and
- 'Safer' substitutes are assumed to be always easily and rapidly available, supported by dense toxicological data to avoid regrettable substitution and risk-risk trade-offs – there is no systemic evidence to support this assumption.

Source: ERIF

There are significant problems with these emerging changes. Most are disproportionate and lack coherence. Their introduction has not taken into account potential unintended consequences, including diversion of resources into defensive R&D; diversion of resources away from safer substitutes; barriers to entry for new substances; reduced dynamism because of the loss of SMEs; loss of the concept of safe use, limiting technologies needed for prosperity, transition and resilience; and systemic uncertainty, making allocation of capital more difficult to justify.

At the same time, the radical changes that are taking place in the traditional model of risk management are being complemented by the progressive introduction of other NRPs to determine market access (and retention) for technologies. It is argued that this new approach will enable the EU to achieve the ideals of a new way of living, producing and consuming. These novel philosophies are designed to be revolutionary and to set **the** standard for global regulatory action.

3.2. 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, exposures and likelihood of harm. Market access for technologies depends upon meeting science-based tests of safety.[24] At EU-level, these requirements are changing. New systemic tests of

24 In a limited number of risk domains, mostly regulated by 'vertical' legislation, additional non-toxic tests of market access have been used in the EU and other jurisdictions in the OECD area. These include tests of efficacy and quality for the approval of new, or improved, human and animal pharmaceuticals, and requirements for 'recyclability' for packaging. These requirements are not systemic or 'horizontal' in their application.

market access are being added that do not focus on protection from damage. 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.

3.2.1. Essentiality

Market access for applications of technologies will, in future, be increasingly determined on the basis of a test of 'essentiality'. Using 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. Safety, based on exposure and likelihood of harm, and safe use, will become secondary considerations and property rights will be weakened.

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 effect of the application of the test of 'essentiality' 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, it 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.

Although the process of refining the implementation of this new risk management test is incomplete, the direction of the trend is clear. Indeed, 'Essentiality' as a test for the use of technologies and hence market access, has

already become embedded in the regulatory culture of the EU. It is, for example, included within the so-called 'Green Taxonomy' rules.[25]

The application of a test of 'essentiality' poses a series of major potential challenges for the future use and development of technologies (**Exhibit 8**).

EXHIBIT 8
ESSENTIAL USE CONCEPT – CHALLENGES

- **Feasibility** – the scale of the application, and subsequent derogations needed for continued use, may be beyond the capacity and capability of the EU Administrative State;
- **Uncertainty** – lack of definitions, exercise of administrative discretion, lack of scientific basis for decisions, inadequate proportionality and weak legal predictability will contribute to systemic uncertainty;
- **Functioning of the economy** – derogations, weak property rights and potentially arbitrary administrative choices will replace some of the traditional norms of commercial society, such as customer choice, competition and support for property rights;
- **Lack of coherence** – a static approach to technology development and loss of technologies critical for prosperity, resilience and transition, may well make it more difficult to achieve ambitious policy goals;
- **Safety and safe use** – the traditional objectives of risk management may become secondary considerations, creating risk-risk outcomes, reducing protection and removing access to critical technologies that, based on existing EU risk assessments, can be used safely; and
- **Trade frictions** – there is, as yet, no evidence that other major trading partners of the EU have, or will adopt, non-toxic tests of market access.

Source: ERIF[26]

25 See for example Regulation (EU) 2020/852 on the establishment of a framework to facilitate sustainable investment and amending Regulation (EU) 2019/2088.

26 See ERIF Highlights Note 16 *Essentiality, Better Regulation and the Management of Risk from Technologies*, 2021.

Its proponents argue that the application of this new test of market access will speed up the transition to 'safe' materials, create greater certainty for market operators and stimulate investment in innovation. In turn, this will contribute to higher standards of protection.

There is, as yet, little evidence to substantiate these claimed benefits. In contrast, the application of the test of 'essentiality' is likely to overwhelm the administrative capacity of the EU, slow down the process of economic evolution, trigger regrettable substitution and risk-risk outcomes, undermine the rule of law and create systemic uncertainty.[27] Innovation is, moreover, unlikely to be stimulated.[28] Taken together, these potential impacts and uncertainties pose a major challenge to the allocation of capital to the EU.

3.2.2. Persistence

Intrinsic properties of persistence, particularly when combined with toxicity, are widely recognised by scientists as a category of hazard that should be subject to public risk management. Restrictions are based on a series of accepted hazard classes that form part of the Globally Harmonised Classification System (GHS), supported, for some forms of persistence, by international treaties, such as the restrictions on Persistent Organic Pollutants (POPs). This is a long-standing and widely accepted approach.

However, properties of material stability will be critical for achieving the EU's political objectives and should be considered a technological asset rather than a liability (**Exhibit 9**).

27 See for example, Montfort, J-P. (2021), "The Concept of Essential Use to Regulate Chemicals – Legal Considerations", *in International Chemical Regulatory and Law Review*, Vol.4(1).

28 See ERIF Highlights Note 19 *Innovation, Essentiality and Better Regulation*, 2022.

EXHIBIT 9

CONTROLLED PERSISTENCE AND DURABILITY

Persistence and durability are highly valued and strategic properties of substances and products. Over many hundreds of years they have been widely, and safely, used throughout the material economy, contributing to high standards of protection, public health and prosperity. These benefits will continue to be highly valued by societies. In the future, these properties will critically contribute to the green transition and greater strategic resilience.

Silicone chemistry, for example, is a critical enabler of the Green Deal. It provides unique benefits of durability and resistance to weathering and high temperature, that extend the life span of EVs, batteries, solar panels wind turbines, modern buildings and electrical devices. In turn, this reduces demand for primary materials, increases the efficiency of new technologies and reduces environmental emissions.

Other forms of complex chemistry also offer important benefits of durability and persistence that facilitate prosperity and make a vital contribution to public health. **PFAS technologies** are a good example. They are used in more than 12,000 applications, many of which are little known. Their functional properties of long duration, effective sealing and lack of reactivity are used throughout upstream chemicals processing industries in membranes and diaphragms, often where there are no substitutes. Used in gaskets, membranes, filters and hose inserts, for instance, these properties enable EU-based vaccine, veterinary medicine and human pharmaceutical facilities to comply with global manufacturing standards, protecting the safety of users and facilitating exports. PFAS technologies are also widely used in critical equipment within major research and development facilities.

Crop Protection technologies help farmers deliver safe, affordable food, whilst limiting the use of scarce resources and reducing environmental impact. Some technologies use durability to provide slow and long-lasting release. This improves efficacy and reduces costs for farmers, helping to support a more sustainable economy.

All **Veterinary Medicine** products require mandatory regulatory approval before being placed on the market. This ensures that products meet regulated standards of quality, efficacy and safety, including an environmental risk assessment that helps to determine safe use. Persistent efficacy is a desirable characteristic for a number of veterinary medicine products. Long-acting, slow release products target parasitic diseases that affect livestock or control fleas and worms that infect companion animals, for example. More complex, slow release technologies allow farmers to reduce the number of doses, contributing to greater animal welfare by reducing stressful manipulation.

Extensive restriction of the use of the properties of durability or persistence is neither desirable nor possible, without major economic damage and a significant deterioration in public health or safety. **The challenge is to make good regulatory decisions that recognise safe use, risk-benefit trade-offs and the time needed to develop safer and more sustainable substances.** New molecules can take between 5 and 8 years to develop and become accepted by users.[29] It is also important to target restrictions, rather than use widespread bans based on non-scientific groups and intrinsic properties, and to ensure that hazard assessments recognise that detection is not hazard and hazard is not harm.

Source: ERIF

The rationale for regulating certain properties of persistence is complex. It reflects, in part, evidence of toxic harm for certain classes of hazard. However, some restrictions are mandated without direct evidence of toxicity of the persistent substance. Such restrictions reflect ethical concerns or beliefs – for instance about the need to protect 'pristine' ecosystems or about avoiding future regrets and uncertainties.

At EU-level, the regulation of 'persistence' is evolving. New hazard classes have been added and new concepts, such as 'mobility', established. There is also a greater philosophic

29 This is a typical development cycle for organic chemicals and similar technologies. In some sectors, the cycle time from discovery to market is longer. In Veterinary Medicine, for example, it takes 10-15 years development and 2 years regulatory approval. (Source: ERIF Research).

emphasis on different forms of 'persistence without toxicity'. In addition, the scope of application of restrictions based on properties of persistence is being expanded, through EU-specific revisions to globally accepted guidance, to encompass more inorganic materials, such as metals and metallic compounds.

These changes in hazard classes are being proposed without a rigorous review of the scientific evidence or of the overall 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 do not align with the globally harmonised classification system.

The application of these new hazard classes and revisions to classification methodologies expands significantly the use of non-toxic tests of market access for technologies in the EU. It also increases the complexity of hazard assessments, creating additional scientific and governance uncertainties (**Exhibit 10**). For example, new tests of 'persistence' pose major scientific challenges, yet to be fully resolved, of the appropriate limits of detection of the presence of technologies. Detection alone, without any evidence of the capacity for toxic harm, may be deemed a hazard, leading to restrictions. As detection technologies become more sophisticated, so more substances are deemed to have persistent intrinsic properties. There are also problems with the relevance of existing standard tests for determining eco-toxicity, the lack of expertise available to EU regulators and the robustness of definitions for new hazard classes.

EXHIBIT 10
PERSISTENCE AND HAZARD ASSESSMENT

'Persistence' is not, in itself, a hazard. It is a property of materials and does not necessarily lead to toxicity. Making high quality assessments about the potential damage to the environment from the persistent properties of materials or bioaccumulation is complex.

It often involves uncertainty, a lack of knowledge or data and extensive interpretation. It requires high levels of relevant expertise. However, the private sector has insufficiently invested in generating relevant modelling and data to overcome these problems. At the same time, many assessments by EU regulators of intrinsic properties of persistence, have not met global standards of quality. Problems include:

- Lack of expertise within scientific committees;
- Undue influence of poor quality or discredited studies;
- Inappropriate influence of the Precautionary Principle within scientific assessments;
- Use of non-standard test methods, species and novel toxicological theories;
- Undue influence of discredited or poor quality studies;
- Selective use of evidence – 'cherry picking'
- Over-reliance on single studies and worst case scenarios;
- Lack of focus on exposure and limits of detection;
- Inadequate use of weight-of-evidence;
- Lack of consistency with underlying scientific evidence;
- Use of inappropriate criteria, methods and species – failure to adapt to specific technologies;
- Failure to modernise test methods and assessments;
- Use of non-harmonised hazard classes, definitions and guidance;
- Failure to follow OECD guidance;
- Extension of scope of assessments without scientific justification – inclusion of inorganic technologies; and
- Lack of proportionality – failure to recognise that detection is not hazard and hazard is not harm.

Source: ERIF

Overall, this expansion of non-toxic hazard classes, and increased complexity of assessments of persistent properties, poses a series of potential challenges (**Exhibit 11**).

EXHIBIT 11
EXPANSION OF 'PERSISTENCE' HAZARD CLASSES – CHALLENGES

- **Lack of recognition of the importance of the properties of 'controlled persistence'** for safety, transition, resilience, prosperity and health (human and animal) and hence need for risk-benefit assessments;
- **Negative consequences of widespread additional mandatory testing** – diversion of resources, including Defensive R&D, loss of SMEs unable to finance additional testing or reformulation, and less investment in substitutes;
- **Lack of evidence of benefits** – new requirements may target social concerns rather than mitigate specific impacts;
- **Stigmatisation of technologies** critical for resilience and transition due to new hazard classifications; and
- **Weakening of well–established vertical assessments of environmental risk and safe use** – through the interaction of new hazard classes with new 'horizontal' risk management mechanisms (groupings, widespread restrictions and tests of essentiality).

Source: ERIF

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.

3.2.3. 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.

Furthermore, extensive private sector investment has flowed into sustainable products and services, supported by voluntary initiatives, corporate reporting requirements, rules for listing on capital markets, demands from investors and widespread sharing of good practices. It is widely recognised that, when properly designed, investments in sustainability can shape corporate cultures positively, create competitive advantage in markets, satisfy emerging customer needs, improve operating efficiency and strengthen human capital. Such investments also respect changes in social attitudes, the underlying basis of the freedom to operate.

Over time, government interventions to promote greater sustainability, beginning with restrictions on environmental damage and depletion and later including interventions to reduce waste and encourage recycling, have become more extensive and ambitious. **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 competing definitions and dimensions, necessitating trade-offs and flexibility. 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. Sustainable outcomes may, moreover, occur primarily throughout complex value chains rather than in specific activities. A further problem is that it is difficult to map and understand the complex contribution to overall sustainability goals of some technologies or activities, such as metals or plastics or the use of non-traditional inputs in manufacturing (**Exhibit 12**).

EXHIBIT 12
SUSTAINABILITY – COMPLEXITIES

Achieving a more sustainable way of producing and consuming is a widely shared political goal. Sustainability is, however, difficult to define and to achieve. There are many trade-offs and complexities that should inform the development of effective policies, including the use of sustainability criteria to determine the development and use of technologies. A number of examples illustrate some of these difficulties:

- **Plastics** – these complex technologies are widely criticised and their use is, in part, stigmatised, primarily because of concerns about persistence and waste. However, their role in enhancing use efficiencies, such as decreasing food waste and reducing greenhouse gas emissions (GHGs), is often overlooked. To understand the impact of plastics compared to alternatives in traditional applications, it is important to look at evidence and science, and not only social concern. Complex analyses, looking at GHGs throughout the entire life cycle, suggest that in traditional applications in packaging, building and construction, consumer goods and automotive, plastic offers competitive, if not lower total GHG contribution than alternatives – especially when benchmarked against the overall performance of the materials.

- **Metals** – understanding the environmental impact of metallic technologies is difficult. Initial processing consumes significant resources and creates major emissions, yet applications are of long duration, there is often significant recycling and many uses deliver major environmental benefits. Initial processing activities also support a very wide range of applications. To identify the net environmental impact of specific applications is complex, requires access to proprietary data to understand the mix of inputs and outputs and cannot be reduced to a single measure or part of a value chain, such as production or refining. If this simplified approach is used, then the initial environmental costs of metals processing may stigmatise the use of metallic technologies.

- **Laundry Detergents** – data from Life Cycle Assessments suggests that 60% of the carbon footprint from laundry activities occurs in people's homes, primarily due to heating water. In contrast, laundry ingredients only contribute 20%. Industry innovation, driven by market forces and customer preferences, can help to reduce the carbon footprint of laundry within the home. Enzymatic technologies, used safely for a number of years, help users achieve lower temperature washing without compromising cleanliness. In turn, this encourages behavioural change and, because of the vast scale of laundry activity, major reductions in environmental damage. For this to continue, policy should take into account the entire carbon footprint of a product and its safe use.

- **Non-Traditional Feedstock** – increasingly, upstream processing industries are seeking to use non-traditional feedstock within their mix of inputs, thereby reducing their environmental impact and progressively decarbonising. This is an incremental change that has been facilitated by the use of international standards to facilitate transparent allocation of the contribution of non-traditional feedstock to the environmental characteristics of specific outputs. It reflects the mixing of inputs and accepts that requiring separate production systems, as an alternative, would create obstacles rather than incentives to more sustainability.

These examples highlight a number of challenges for the increased use of sustainability as a non-toxic criterion for market access. Measurement is complex and short cuts, which lead to simplification, could have significant unintended consequences. In this respect, companies and Trade Associations could further develop the robustness of their socio-economic analyses, and publish more comprehensively and transparently the assumptions, economic modelling and standardised data used in their studies.

Good policy should focus on outcomes not processes, and systems rather than products or inputs; safe use should be protected; standards provide flexibility, whereas legislation may impede progress; incremental change should be encouraged; and incentives should be strengthened.

Policy design should also recognise that ideas should be feasible, particularly for SMEs, and systematic uncertainty should be avoided.

Sources: ERIF, McKinsey[30]

Overall, good policy should focus on outcomes, accept incremental change and complexity, recognise trade-offs and avoid prescriptive solutions.

The EU's approach set out in the Green Deal is highly ambitious. 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 change throughout the EU economy, on an enormous scale. [31]

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 (**Exhibit 13**).

EXHIBIT 13

APPLICATION OF THE SUSTAINABILITY CONCEPT – TRENDS AND CHALLENGES

- Development of soft law instruments, such as guidance and platforms to share methodological tools on safety and sustainability, for instance through the work carried out by the JRC and DG RTD. The effectiveness of these mechanisms will largely depend on the robustness, validity and adequacy of the 'ex-ante' methods and modelling tools that will be used;

30 McKinsey & Company (2022), *Climate Impact of Plastics*.

31 For example, analyses carried out as part of the EU's Green Taxonomy, suggests that less than 10% of current economic activity within the EU meets its ambitious and extensive sustainability goals.

- All three elements of the wider definition of sustainability (ESG – environmental, social and governance) are embedded and all have equal importance, requiring significant guidance for implementation;
- Complex trade-offs between different sustainability goals, and between sustainability, safety and safe use, leading to possible risk-risk outcomes;
- Apparent focus on 'inputs' (substances, products, production processes or methods, product categories) rather than 'outcomes', and on individual products or processes rather than 'systems';
- Interaction between sustainability interventions and other NRPs, most notably defining safety on the basis of intrinsic properties, rather than using likelihood of harm to determine safe use, thereby reducing the available range of critical technologies; and
- Progressive inclusion of mandatory sustainability criteria in regulatory requirements, either to inform consumers or to direct investment, thereby establishing a formal test of market access.

Source: ERIF

If these trends are confirmed, 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 workable definitions and methodologies. The impact of these problems may be amplified by the interaction between the new sustainability mechanisms and other NRPs, and by the scale and pace of regulatory change.

Progressively these complexities and challenges may undermine incentives to innovate, to invest in more sustainable products and processes and to allocate capital to the EU. There is an emerging risk that, as a result of a lack of coherence, there will be a conflict between the political 'ends', that are widely

supported, and the policy 'means' by which regulators have chosen to pursue them.

3.3. Direct Steering of Investment – 'Upstream' Novel Approach

Novel approaches in the EU to managing risk, and hence to the management of technologies, encompass a growing range of initiatives, including regulation, designed to direct investment by the private sector into forms of finance, innovation, operating processes and markets that are considered socially desirable. This is the 'upstream' dimension of the typology of NRPs being adopted at EU level. Examples at EU-level include the EcoDesign for Sustainable Products Regulation and supporting policies, as well as the inclusion of sustainability requirements, in addition to traditional restrictions on environmental emissions or workplace exposures, in operating licences for manufacturing facilities.

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 origins of the SSbD concept lie in engineering science. Engineers, using safe technologies, seek to design sustainable and controllable systems. Safety and safe use of technologies, based on likelihood of harm, are critical preconditions for the application of this long-established approach. Increasingly, SSbD ideas have informed investment decisions by companies, adding an additional criterion to innovation decisions but without excluding traditional goals of cost, price or product performance.

Globally a series of initiatives have built on and articulated the trend towards greater embedding of sustainability goals in major investment decisions. This has occurred primarily through the development of voluntary guidance. Initiatives include US Green Chemistry, OECD Guidance, corporate guidelines, financial reporting guidance and the

European Commission's Joint Research Centre and the Directorate-General for Research and Innovation guidance in the EU.[32]

From these initiatives, **an overall framework of good practices, set out in guidance**, has emerged for the effective application of SSbD (**Exhibit 14**).

EXHIBIT 14
SAFE AND SUSTAINABLE BY DESIGN – GOOD PRACTICES

- Share good practices, particularly for SMEs;
- Ensure workability of good practices for SMEs;
- Recognise the importance of risk-benefit trade-offs for achieving complex goals;
- Strengthen 'value drivers' within the private sector, focusing on factors such as, customer preferences, operating efficiency, competitive advantage, business culture and corporate reputation;
- Recognise the heterogeneity of sectors, markets and value chains and hence the different ways in which sustainability goals can be achieved. Standards and practices are, therefore, targeted and specific rather than "one size fits all";
- Accept that safety is a precondition, based on likelihood of harm, and that the safe use concept is critical for access to some of the most efficacious technologies needed for sustainability;
- Avoid using scoring systems that are simplistic or fail to provide appropriate contextual information; and
- Focus on outcomes, incentives and systems rather than direction, products and inputs.

Source: ERIF

32 See for example OECD (2021), *Guidance on Key considerations for the Identification and Selection of Safer Chemical Alternatives*, OECD Series on Risk Management No. 60; European Commission (DG RTD) (2021), *Mapping Study for the development of Sustainable-by-Design criteria*; European Commission (JRC) (2022), *Safe and Sustainable by Design Chemicals and Materials: Review of Safety and Sustainability dimensions, aspects, methods, indicators and tools*, JRC Technical Report; and Florin, M-V. et al. (eds.) (2023), *Ensuring the environmental sustainability of emerging technologies*, EPFL-IRGC.

Whilst many of these good practices have been identified and championed by the European Commission's JRC and DG RTD, the interaction of the SSbD concept with other NRPs gives rise to a series of different characteristics and challenges, most notably if it is embedded in legislative and regulatory requirements (**Exhibit 15**). Examples at EU-level include the proposed Eco-Design for Sustainable Products Regulation and the inclusion of sustainability requirements in operating licences for manufacturing facilities, in addition to traditional restrictions on environmental emissions or workplace exposures.[33]

EXHIBIT 15
SSBD AT EU-LEVEL – TRENDS AND CHALLENGES

- It is likely to be applied 'horizontally', through framework legislation complemented by specific delegated acts, limiting effective scrutiny;
- It may make use of 'one size fits all' criteria or simplistic scoring systems that might be too generic and fail to reflect fully and usefully differences within individual product categories and value chains;
- It may be unworkable and too complex for SMEs, limiting its application and creating disincentives for investment in safer and more sustainable operating processes and products;
- It may use intrinsic properties (including new hazard classes included in recent revisions of risk management legislation) as cut-off criteria to determine the exploitation of material technologies in all new products, allowing safe use of critical substances and materials only through explicit derogation in a small number of applications based on the 'essentiality' test. This will limit the availability of critical technologies needed for achieving greater sustainability;

33 See European Commission (2022), *Proposal for a Regulation establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC*, COM(2022) 142 final; and European Commission (2022), *Proposal for a Directive on amending Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste*, COM(2022) 156 final/3, respectively.

- It may focus on 'negatives' or 'inputs' rather than outcomes – bans on inputs, production processes or methods and product categories, rather than creating incentives for investment in safer and more sustainable end-points; and
- It may fail to accept risk-benefit trade-offs, creating potential risk-risk outcomes and regrettable substitution, as well as inhibiting incremental improvements, limiting investment and restricting the evolution of technological possibilities; and
- It might result in a static vision of the present technological frontier, jeopardising potential innovation advances and unknown future benefits.

Source: ERIF

Finally, the scale and timing of the envisaged change is unprecedented across the OECD area, posing major challenges of effective implementation, administrative capacity and competence, and for the application of Better Regulation policies, processes and tools.

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. These will 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.

4. Risk management and the EU's political goals

This section examines the relationship between the EU's political goals and risk management policies. It identifies the importance, for achieving the green transition and greater strategic resilience, of creating incentives for the allocation of capital and for the exploitation of material technologies. In turn, it highlights the need to understand the potential impact of adopting novel risk management philosophies on the private sector decision-making processes that determine how capital is allocated and how resources are invested in developing and using material technologies. The costs and benefits of new ways of managing risks should be primarily assessed against these two factors.

The arguments set out in this section are supported by several examples from a variety of sectors and technologies, directly drawn from the ERIF programme of in-depth interviews and the literature review. The scope of the economic activities considered directly illustrates the wide-ranging and fundamental implications that the NRPs have across the EU economy.

4.1. Management of Risk and Technologies for the Green Transition and Greater Strategic Resilience

The European Green Deal is the most ambitious policy programme of the European Union in a generation. It seeks to deliver a "greener", more prosperous, more sustainable and more inclusive future. More than a new strategy for growth, it aims to trigger a social and economic revolution.[34]

The European Commission, supported by the EU co-legislators, has overseen the design and articulation of the Green Deal, demonstrating an exceptional and pioneering political commitment to comprehensively re-organise the EU-level policy and decision-making process. This is to be commended and is needed for the achievement of the two overarching policy goals – **the Green Transition and greater Strategic Resilience.** These are the ultimate political 'ends' pursued by the Green Deal. More specific objectives include achieving zero net carbon emissions by 2050; decoupling economic growth from resource use; protecting, conserving, and enhancing Europe's natural capital; and protecting the health and well-being of citizens from environment-related risks and impacts.

34 See ERIF Highlights Note 13 *The European Green Deal and Better Regulation*, 2020.

Identifying and exploiting the opportunities offered by driving the transition of the European economy to more sustainable performance is critical, not only for the overall competitiveness of the bloc but also for the prosperity and well-being of European citizens. With its commitment to the Green Deal, the European Commission has set out to shape the industrial policy of the entire European Union. Policies and initiatives designed centrally at the EU level are preferred to merely coordinating Member States efforts, as occurred with previous attempts to guide economic transformation such as the "Lisbon Agenda" in the early 2000s.

Making the EU's economy more strategically resilient, and hence better able to absorb major geo-political shocks, is a similarly important political goal. It seeks to reverse longer-term trends towards the off-shoring of value chains away from the EU, which have led to importation of key technologies and de-industrialisation in strategic sectors, whilst at the same time retaining existing value chains, productive capacity and development of key technologies. A declared objective is to persuade investors to 're-shore' economic activities and technologies, thereby rebuilding the EU's economic eco-system.

Whilst there is widespread support for the political 'ends' that the EU is pursuing, it is appropriate to appraise whether the policy 'means' chosen by the EU policy-makers are likely to be effective and proportionate or may prove counter-productive. In this respect, **any assessment of the effectiveness of the NRPs being adopted at EU-level, should consider the positive and negative impacts these are likely to have on achieving the twin goals of the green transition and greater 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.**

4.2. Capital Allocation and the Green Transition and Strategic Resilience

If the political goals of the green transition and strategic resilience 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. Capital investment will be required on a massive scale. There is no

shortage of capital as such but capital needs to be allocated to the delivery of the Green Deal in preference to other uses, jurisdictions or returning to stakeholders (whether investors or taxpayers).

Delivery of the Green Deal and greater strategic resilience will happen in reality only thanks to the investment decisions made by a multitude of stakeholders in both the private and public sectors.[35] **For this to happen, policy-makers need to have an informed understanding of how capital allocation decisions are actually made by the private sector. Indeed, all policy initiatives should be tested against it** – including the adoption of NRPs for the management of risk.

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. **This 'investment' process is separate from and, in general, not influenced by financing decisions.** Within the allocation of capital process, there are three inter-linked groups of decisions, and public policy interventions can affect all of them (**Exhibit 16**).

EXHIBIT 16
ALLOCATION OF CAPITAL PROCESS – KEY DECISIONS

1. **Strategic Risks – allocation of corporate resources recognises that there are differences in the types of risk 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 on the use of critical technologies, and diversion of investment resources away from innovation, thereby limiting the development and protection of competitiveness.

35 Private investment already represents more than 85% of total investment in the EU. (Source: European Commission (2023), *Communication on Long-term competiveness of the EU: looking beyond 2030*, COM(2023) 168 final). The pivotal role that private sector investments play to achieve the Green Deal objectives is also underscored by a recent report of the European Court of Auditors. See European Court of Auditors (2023), *EU climate and energy targets. 2020 targets achieved, but little indication that actions to reach the 2030 targets will be sufficient – Special Report*, Luxembourg.

Within this framework of strategic risk assessment by private sector firms, **the EU must compete with other regional economies, such as North America, South America and Asia, for the allocation of capital**.

2. **Framework conditions – public policy and the regulatory environment play a major role in creating incentives for companies to invest, particularly in innovation.** At the same time, regulatory factors, including policy, law making and the implementation of legislation, can distort framework conditions and inhibit investment. Framework conditions for investment in innovation are driven by three groups of factors:

   - **Social attitudes**, particularly towards new ideas, risk-taking, precaution and new technologies;
   - **Demand factors**, including access to markets, consumer confidence, use of competitive strategies, market size and adoption of new ideas and technologies; and
   - **Availability of critical inputs**, particularly ideas (including access to upstream and other 'platform' technologies) and capital, and their diversion into Defensive R&D.

3. **Investment economics – the balance of risk and reward identified for individual investment projects.** These assessments are generally based on widely accepted principles of corporate finance.[36]

   - Successful projects must meet or exceed the risk-adjusted cost of capital, after taking account of project-specific risks;
   - Project-specific analyses take into account expected positive cash flows (enhanced margins or reduced costs) less negative cash flows (capital expenditure, development costs, operating costs) discounted at the cost of capital over the project horizon.

36 See Brealey, R.A., et al. (2020), *Principles of Corporate Finance*, McGraw-Hill Education.

This means that cash flows received in later periods are worth less and has the effect of penalising delays, including those induced by regulatory testing and approval requirements and by processes that slow down time-to-market;

- **The cost of capital used for investment decisions is a risk-adjusted opportunity cost set by global capital markets** using well-understood techniques, such as the Capital Asset Pricing Model. It is not, in general, determined by sources of financing;
- Financing decisions are separate from investment decisions;
- Financing decisions focus on factors such as gearing, solvency, liquidity, 'matching' (cash flows and types of assets and liabilities) and servicing costs;
- Funding for companies is derived, ultimately, from two sources: decisions by 'savers' to defer consumption or protect assets, and use of retained earnings generated by previous corporate profitability;
- Corporate valuations reflect forecast future cash flows discounted at the cost of capital, recognising the many complex and sophisticated factors that can impact future performance, including intangibles such as reputation, property rights and management quality.

Source: ERIF[37]

The potential impact of NRPs on the capital allocation process needs to be rigorously assessed. Of particular importance will be their potential impact on strategic risk. Policies, such as risk management, that create systemic uncertainty, weaken property rights, undermine scientific integrity or destroy existing business value, for example, will make it harder to justify the allocation of capital to the EU. The policy 'means' could then limit the achievement of the political 'ends'.

37 See ERIF Highlights Note 18 *Allocation of Capital, Better Regulation and the Delivery of the Green Deal*, 2022.

4.3. Material Economy and the Green Transition and Strategic Resilience

One of the most important critical success factors for the delivery of the Green Deal and greater strategic resilience is the retention and exploitation of the industries, value chains, and technologies of the material economy (metals, biology, chemicals, and biotechnology). Achieving this will, in part, depend upon the allocation of capital to the EU. It will also be influenced by the extent to which policies, including risk management, create incentives to innovate and stimulate dynamism, particularly amongst SMEs.

Exploitation of material technologies, and their complex properties, will play a major role in delivering the political goals of the green transition. They are of critical importance, for example, for mobility, energy storage, new and renewable forms of energy, transmission of energy, reduced emissions and environmental damage, greater circularity and facilitating changes in consumer and user behaviour (**Exhibit 17**).

EXHIBIT 17
MATERIAL TECHNOLOGIES AND THE GREEN TRANSITION

Material technologies, particularly metals, chemicals, biology and biotechnology, are the foundations on which our way of life is built. Achieving the transition to a more sustainable economy will depend, to a significant extent, upon the effective exploitation of the complex properties of material technologies. This process has already begun, delivering measurable improvements in environmental impact. Good regulatory decisions take this into account, when considering risk-benefit trade-offs. The importance of material technologies for the green transition can be illustrated by a number of examples, specifically:

- **Polycarbonates** – these are complex speciality plastics with unique properties. They are fully recyclable mechanically or chemically and are a material of choice in applications important for strategic resilience, such as automotive, electrical and electronics, building and construction and healthcare.

In healthcare, for example, polycarbonate materials are of critical importance for the effective treatment of kidney disease via dialysis. Their environmental impacts are also significant. For example, polycarbonate technology is used in automotive components to reduce weight, thereby cutting energy consumption without compromising safety. LED lighting can withstand high temperature deviations and harsh conditions thanks to polycarbonates. Battery casings in Electric Vehicles (EVs) use polycarbonates. The sector is also highly innovative, creating new carbon neutral materials for example.

- **Adhesives and Solvents** – products based on these advanced formulations provide bonding and sealing solutions to a significant part of the EU's industrial economy. These include major environmental benefits. Their properties facilitate energy efficiency, material efficiency, repairability, durability and recycling. In the automotive sector, for instance, they enable the use of composite materials, reducing weight and fuel consumption. Similarly, they enable the use of composites for wind turbine blades, making renewable energy generation more economically feasible. In the construction sector, the widespread use of adhesive and sealant products helps improve material efficiency through less waste and more advanced construction methods, as well as cutting energy use and reducing GHG emissions by up to 80% through improved thermal insulation.

- **Cobalt** – the properties of cobalt metallic technologies are of critical importance for the green transition. Batteries used for energy storage, mobility, building and construction, digital infrastructure and consumer electronics, rely upon cobalt technology for properties such as safety and longevity. Cobalt compounds are used as catalysts to improve the quality of fuels and to reduce GHG emissions from thermal engines. Complex alloys containing cobalt and exploiting its properties are used in wind turbines, jet engines, process pipes and valves, as well as high wear applications in nuclear energy production and defence.

Cobalt in hard metal enables some of the most efficient cutting and drilling tools used across industrial and professional applications. Cobalt technologies also contribute to health, as a micro-nutrient in animal feed and in many medical devices, such as orthopaedic implants. (Cobalt is also one of thirteen critical and strategic raw materials identified by the EU in the Critical Raw Materials Act.)

- **Silicone chemistry** – these unique materials, offering important properties including heat resistance, durability and thermal stability, play an indispensible role in the transition to a more sustainable economy. In building and construction, for example, silicone chemistry is used in structural glazing, improving energy performance. It is also widely used in the generation of renewable energy, for example in encapsulants for solar panels and in lubricant additives that improve the power generation of wind turbines by up to 8%. In the nuclear sector, silicone chemistry provides coating and encapsulation of electrical and electronic applications in nuclear power plants.

Source: ERIF

Achieving greater strategic resilience also depends on investment in the EU in material technologies. Policy-makers understand the importance of retaining existing value chains and technologies, as well as re-shoring critical activities. Material technologies are central to this. Upstream industries, such as metals processing, chemicals and advanced polymerisation, provide products and technologies for complex downstream applications, including high technology activities such as aerospace, defence equipment, pharmaceuticals, medical equipment and motor vehicles. They also support major consumer value chains. Taken together, these economic activities provide jobs, wealth, safety, well-being and prosperity, as well as greater strategic resilience (**Exhibit 18**).

EXHIBIT 18

MATERIAL TECHNOLOGIES AND STRATEGIC RESILIENCE

Achieving greater strategic resilience is one of the EU's most important political goals. It is a means of enhancing the capacity of the EU to absorb geo-political shocks and to respond more effectively to unforeseen threats to public health, such as the COVID-19 pandemic. In part, this will be achieved by ensuring the location within the EU of complete value chains, from upstream processing to downstream applications, of critical material technologies.

Whilst a series of measures have already been enacted, focusing on issues such as access to raw materials and critical technologies, the way in which risk is managed will play a major role in influencing the extent to which the EU is able to re-establish major value chains based on material technologies. Parts of many material value chains have already moved away from the EU. Policy, legislative and regulatory decisions should take these factors into account, so that risk-benefit trade-offs can be understood fully and negative unintended consequences avoided. It should also recognise that interventions should create incentives, rather than obstacles or prescription, for the allocation of capital to the EU.

The importance of material technologies for greater strategic resilience can be illustrated by a series of examples. Specifically:

- **Precious Metals** – the importance of metals such as gold, silver and platinum for the resilience of the EU economy is insufficiently understood. In healthcare and public health, for example, their properties are used in wound control, water treatment, cancer treatment and medical devices, whilst catalytic converters reduce harmful emissions from motor vehicles. Precious metals are also critical for the functionality of semi-conductors, digital devices and missile technology. In the aerospace sector, they are used in alloys, coatings and soldering to provide, amongst functional benefits, protection against high temperatures and corrosion in electronics, landing gear and airframes.

- **Plastics** – plastic technologies, including advanced polymerisation, remain critical to the functioning of the material economy and hence the capacity of the EU to strengthen strategic resilience. Major downstream users of plastics include building and construction, packaging, aerospace, automotive and healthcare. Looking solely at activities in production, conversion, recycling and machinery manufacturing, plastic technologies support more than 1.5 million direct jobs in over 52,000 businesses. Plastic technologies are also contributing extensively to the green transition, including providing advanced polymers for wind turbines, reducing the weight of motor vehicles and protecting the safety of digital equipment through flame retardant materials.

- **Nickel** – the complex properties of nickel, in its various forms, provide a set of enabling technologies that support a large-scale value chain that is of significant importance for the strategic resilience of the EU. Taking into account recycling, direct processing and extraction, first use and end use, the nickel value chain supports more that Euro 50 billion GVA. Major first uses include stainless steel manufacturing, alloy production, surface coatings, castings and the production of nickel chemicals for applications such as batteries for energy storage and EVs. Important end uses that depend upon the unique properties of nickel technologies include aero engines, gas turbines, chemical processing, building and construction, food processing and preparation and medical devices. Nickel is, in addition, a critical technology for electrification and mobility, including its use in batteries, thereby contributing to the green transition.

Source: ERIF

The regulatory framework, including the regulation of risk, will have a major influence on the ability of the EU to secure additional investment in material technologies, including greater allocation of capital to first use sectors in upstream industries and high-tech sectors generally. It will be more difficult to justify the allocation of capital to these activities in the EU, if regulation creates systemic uncertainty, reduces access to safe technologies, weakens property rights, undermines the competitiveness of downstream users of technologies,

erodes value in capital intensive or high technology sectors, or impairs the dynamism of SMEs.

Any assessment of the costs and benefits of the adoption by the EU of NRPs to manage risks, should consider the direct and indirect impact on incentives to utilise the properties of material technologies and to invest in their production and application in the EU.

5. Novel regulatory philosophies – assessment of benefits and costs

This section considers the potential benefits and costs of the use by the EU of NRPs for the management of risk and hence the development and use of technologies. It assesses critically the potential benefits (section 5.1.). It identifies possible costs (5.2.). Finally, it considers the extent to which benefits justify costs, along with issues of potential regulatory failure (5.3.).

5.1. Benefits

EU policy-makers argue that the implementation of the EU's new risk management approach will deliver significant economic, social, health and environmental benefits. Greater protection of health and the environment will lead to consequential reductions in mortality and morbidity, as well as improved environmental quality. In addition, directing technology use and development, will stimulate greater strategic resilience and transform the EU's economy, making it safer, more sustainable and a global leader.

5.1.1. Health and Environmental Improvements

Improved health and environmental outcomes are tangible benefits that the new approach to risk management is expected to deliver. However, considerable controversy surrounds the specific intervention logic used to justify these potential benefits. **Many eminent scientists argue that there is no robust evidence to support the claimed presence of health or environmental risks that fall outside the existing legislative framework and hence pose unregulated threats to man or nature.**[38]

The justification of the new radical approach lacks rigour with respect to a critical, systematic and unbiased review of the available evidence. Rather, the proponents of the use of NRPs characterise health and environmental problems more on the basis of social concerns, perceived risks and unverified assumptions. Trends in human and environmental

38 See for example Bridges, J.W., et al. (2023), "Is the EU chemicals strategy for sustainability a green deal?", in *Regulatory Toxicology and Pharmacology*, Vol.139; Barile, F.A. et al. (2021), "The EU Chemicals strategy for sustainability: In support of the BfR position", *Archives of Toxicology*, Vol.95, and Herzler, M. et al. (2021), "The EU chemicals strategy for sustainability questions regulatory toxicology as we know it; is it all rooted in sound scientific evidence", in *Archives of Toxicology*, Vol.95. Senior officials from the German Federal Institute for Risk Assessment (BfR) submitted the last article.

health indicators are not correlated to reliably measured exposures but, simplistically, to the mere presence of intrinsic properties of technologies. These arguments do not appear to support claims that there are significant unregulated harms leading to health or environmental damage, or that traditional risk management procedures and methods, based on the likelihood of harms, are systemically flawed.

Moreover, hazard is not harm, and detection is not hazard. The elimination of hazards, if at all possible, may well not be desirable. It does not necessarily lead to improvements in health or environmental standards, and may, over time, reduce protection and safety.

Indeed, the EU has one of the most effective and comprehensive regulatory frameworks in the world for the management of risks. **There is a lack of robust evidence of regulatory gaps or new threats that cannot be managed by existing laws.**

5.1.2. Framework Conditions for Investment and Innovation

Alongside better protection for health and environment, it is argued that the adoption of NRPs will improve framework conditions for investment in innovation and the allocation of capital to the EU. This will be achieved through two mechanisms: better quality regulatory decisions; and the use of restrictions to force the widespread mandatory substitution of safe for so-called 'unsafe' technologies, substances, products and processes.

- **Better quality decisions** – it is argued that the application of the NRPs will make decision-making processes speedier, more certain, more effective and cheaper.

  However, the adoption of the doctrine of 'essentiality' combined with recourse to widespread restrictions based on groupings and intrinsic properties is likely to lead, for example, to an enormous number of requests for derogations. This may well overwhelm the capacity of the EU's Administrative State and significantly increase the number of litigation cases, leading in turn to slower decision-making, diversion of resources, economic disruption, regulatory unpredictability and the erosion of property rights. It may also lead to losses of critical inputs, revenues and margins for SMEs, many of which lack the financial capacity to absorb such changes.

At the same time, expansion of the scope of risk regulation, along with the expansion of testing and hazard classes, will divert resources into Defensive R&D, further limiting dynamism in the economy and slowing down investment in safer and more sustainable alternatives.

There is little evidence that the implementation of NRPs will improve the speed, quality or cost of regulatory decisions. Instead, 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.

- **Widespread forced substitution and market opportunities** – it is also argued that the widespread use of bans and restrictions of technologies, on the basis of their intrinsic properties, will rapidly remove an extensive range of substances and products from the market. The application of the so-called Substitution Principle will, it is believed, 'clear a space' in markets, thereby creating a stimulus for investment in new safe and sustainable substitutes.[39]

There is, however, a lack of robust, systemic evidence to support these claimed benefits. Capital is not necessarily allocated to replacing lost technologies or applications. There is little evidence that safer or more sustainable alternatives offering similar efficacy and benefits, are easily or quickly available. Innovation does not occur because of direction by governments. Substitution requires significant time and alternative technologies may, as yet, be unavailable. Indeed, regulators lack knowledge about how technologies function or are used and are unlikely, therefore, to be able to target substitution interventions, leading instead to widespread economic disruption. The continued availability of technologies critical for the green transition and strategic resilience, may also be threatened because bans based on intrinsic properties remove the concept of safe use. Finally, one of the most likely outcomes is an increase in net risk because of adverse risk-risk trade-offs, as users switch behaviours or use less well-understood alternatives.

39 The Substitution Principle has become a cornerstone of the EU's novel approach to managing the use and development of technologies. Its most important underlying assumptions are 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.

Assessments of the widespread application of the Substitution Principle suggest that it is unlikely to create significant incentives to invest in innovation and may increase net risk to health or the environment.[40]

5.1.3. Global Competitive Advantages

The adoption of a radical new approach to the management of risk will, it is argued, help trigger an economic "renaissance". The EU will become a global leader, anticipating changes that other jurisdictions will make in the future, creating 'first mover' advantages for EU-based companies competing in global markets and attracting capital seeking to benefit from participating in a world-leading market.

In some policy domains, such as data flows, privacy and competition law, the EU influences strongly the development of the regulatory framework adopted by other jurisdictions. Moreover, research by the OECD illustrates the role of the EU as a "thought leader" in some areas of regulatory management. Aspects of the EU's Better Regulation programme, particularly its scope, guidance and processes, are seen to be amongst the best in the OECD area.

Looking at risk regulation frameworks, there is evidence that governance solutions introduced by the EU institutions have been considered by other jurisdictions. Some of the EU's implementation mechanisms, such as the scientific assessments of the European Medicines Agency or the world-leading guidance for the risk assessment of cosmetics created by the Scientific Committee on Consumer Safety (SCCS), have become examples of best practice.

In contrast, adoption by other jurisdictions of the EU's wider approach to the management of risk has been partial or conditional:

- In some Asian counties, for example, parts of the EU's REACH policy for chemicals management have been utilised, primarily requirements to register substances and provide evidence of properties, exposures and applications. In turn, this information, generated by producers, has provided national regulators with an informed and rational

40 See for example Löfstedt, R. (2014), "The Substitution Principle in chemical regulation: a constructive critique", in *Journal of Risk Research*, Vol. 17(5).

basis for prioritisation of interventions and for developing risk management measures based on the principles of the likelihood of harm approach.

- Some jurisdictions, such as Canada, have adopted a formal Precautionary Principle. Its application, however, remains primarily restricted to the legitimation of specific risk management measures, with its implementation structured by extensive guidance.

- Finally, some US States have introduced precautionary measures, based partly on intrinsic properties, for the management of the development and use of technologies. The scope of these measures is, however, restricted to the specific States and their implementation is restrained by wider legal and constitutional protections. Risk management by the US Federal government remains, in contrast, based on likelihood of harm, science, exposure, safe use and safety.

In general, however, and recognising a few limited exceptions, non-EU jurisdictions are not adopting the NRPs 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. The non-EU approach has a number of distinctive characteristics (**Exhibit 19**).

EXHIBIT 19
NON-EU POLICIES FOR RISK MANAGEMENT AND ECONOMIC TRANSFORMATION – CHARACTERISTICS

- Risk management continues to be based on the principles of likelihood of harm: the traditional approach predominates;

- Safety, using the traditional approach, remains the primary criterion for market access;

- Policies focus, in general, on the benefits of technologies, thus ensuring safe use based on likelihood of harm;

- Significant emphasis on retaining the existing industrial base and exploiting the complex technologies of the material economy;
- Green transition is a widely shared goal, but the path is more measured, grounded in empirical evidence, coherent and aware of complex trade-offs;
- Policy design is more coherent, recognising that risk management regulation plays a critical role in creating framework conditions, as well as determining access to critical technologies and allocation of capital; and
- Technology development policies emphasise incentives, technological neutrality, investment economics, progressive change, markets and outcomes, with supporting risk management philosophies based on likelihood of harm, science, proportionality and predictability.

Source: ERIF

The recent US Federal Policy for Biotechnology and the wider Inflation Reduction Act illustrate many of these characteristics (**Exhibit 20**).

EXHIBIT 20
TECHNOLOGY MANAGEMENT, INNOVATION AND ALLOCATION OF CAPITAL – US EXAMPLES

In general, non-EU jurisdictions retain the traditional approach to risk management and, compared to the EU, utilise a different mix of policies to promote the allocation of capital, and investment in innovation, to support greater sustainability and prosperity.

The United States policy for the promotion of biotechnology, a critical technology for the green transition, illustrates this approach.

Based on the President Biden's 2022 Executive Order on Biotechnology and Bio-manufacturing,[41] the policy takes a horizontal, 'whole-of-government' approach. It seeks to stimulate investment so as to harness the power of biology to improve health, sustainability, resilience, competiveness and national security. It explicitly encompasses policy, implementation and oversight.

This example reflects a number of good regulatory principles and practices, including:

- **It is technologically neutral** as it focuses on biology and makes no distinction between the different types of biological technologies, such as gene editing, genetic modification or fermentation.
- **It focuses on strengthening incentives** to allocate capital, targeting measures at improving framework conditions and creating favourable investment economics.
- **Framework conditions are to be strengthened** through investments in ideas, including foundational science and commercialisation, standards for biological data, worker training, and regulatory reform.
- **Regulatory requirements should ensure safe use** of biological technologies, with measures being science and risk-based, proportionate and efficient.
- **Regulatory obstacles that increase time-to-market should be removed.**
- **Investment economics, for individual projects, are to be enhanced** through financial measures to reduce capital investment in piloting and prototyping and to support demand for bio-based processes, products and services, such as bio-energy.
- **Governance requirements**, including ex post evaluation, implementation milestones, and institutional oversight, are set out clearly.

41 See US Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President, *Advancing Biotechnology and Bio-manufacturing Innovation for a Safe, Sustainable and Secure American Bio-economy*, Executive Order 14081, September 12, 2022.

In contrast, the EU has taken a different approach. Regulatory measures are technology-specific, precautionary and disproportionate. It is assumed in the EU that everything that has not been approved is forbidden, instead of everything being approved unless it is forbidden. Regulation seeks to direct the use of biotechnology into a limited range of applications, based on societal concerns, and creates barriers to application and investment, including stigmatisation and extended time-to-market. These obstacles have led to negative economic and social impacts.

Whilst significantly larger in scale, the US Inflation Reduction Act, designed to promote investment in more sustainable technologies, processes and products, is similar in design to the US policy for biotechnology. It creates certainty, works with markets and incentives, ensures access to critical technologies, limits prescription and direction, embeds regulatory predictability and safe use, targets investment decision-making and makes potentially risky projects more attractive.

Source: ERIF

Recent research by the OECD poses further questions for the likely effectiveness of EU's adoption of NRPs as a means of stimulating an economic revolution.[42] It identified a series of challenges facing so-called 'mission' policies designed to direct the business sector to solve social problems. There is, as yet, no evidence that such policies are effective or sufficient. There is, moreover, a risk of 'capture' by vested interests, leading to anti-competitive behaviour and protectionism. A further problem is that the rationale for the adoption of this type of policy uses parallels with wartime that are inappropriate and reinterprets, from an ex post perspective, the effectiveness of governments in directing technological change. Finally, OECD researchers could find no robust evidence to support the hypothesis, advanced by Michael Porter in the 1990s, that forcing business through regulation to change technologies and solve social problems, leads to positive economic outcomes or so-called "first mover advantages" in global markets.[43]

42 See OECD (2022), *Industrial Policies in OECD Countries – Are industrial policy instruments effective?*, OECD STI Working Paper.

43 See for example, Porter, M.E. and C. van der Linde (1995), "Toward a New Conception of the Environment-Competitiveness Relationship, in *Journal of Economic Perspectives*, Vol. 9; and Ashford, N. et al. (1985), "Using Regulation to Change the Market for Innovation", in *Harvard International Law Review*, Vol. 9.

The OECD does, however, conclude that policies focused on strengthening framework conditions and creating incentives, including changing the balance of risk and reward for investment projects, had a positive effect on allocation of capital and greater competitiveness.[44] In general, the 'pull' approach, based on incentives and investment economics, had a more beneficial effect than 'push' policies that employ command and control, direction and prescription.

There is, as yet, no evidence that the approach taken by the EU to the management or technologies, through the adoption of NRPs, will lead to an 'economic renaissance', create global competitive advantage or stimulate allocation of capital to the EU and away from other jurisdictions.

5.2. Costs

The NRPs 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 (section 5.2.1.);
- Loss of critical technologies needed for the green transition and strategic resilience (5.2.2.);
- Systemic uncertainty (5.2.3.);
- Diversion of resources away from investment in safer and more sustainable technologies (5.2.4.);

44 OECD (2022), *An Industrial Policy Framework for OECD Countries*, OECD Publishing.

- Reduced incentives to innovate (5.2.5.);
- Structural damage to the eco-system of SMEs (5.2.6.);
- Erosion of competitiveness of formulator industries (5.2.7.); and
- Destruction of value for major industries (5.2.8.).

5.2.1. Reduced Protection of Health and the Environment

Public management of risk, including potential harms to human health and the environment, is one of the core functions of the modern State. The adoption of the NRPs is expected to drastically strengthen protection of health and the environment.

However, the implementation of the EU's novel approach to risk management may in reality reduce safety and erode protection of health and the environment for the following reasons:

- Decisions based on intrinsic properties may **undermine the safe use concept**, leading to the loss of use of substances critical for health, safety and environmental protection – for example the loss of 'controlled toxicity' and 'controlled persistence' (as illustrated in Exhibits 3 and 9);
- **Safety and safe use may become secondary considerations behind non-toxic criteria;**
- Forced substitution may **increase net risk** because of **risk-risk** outcomes due to behavioural change or the greater use of alternatives with less well-understood intrinsic properties;[45] and

45 See Wiener, J. and J. Graham (1995), *Risk versus Risk: Tradeoffs in Protecting Health and the Environment*, Harvard University Press; and J. Wiener (1998), "Managing the Iatrogenic Risks of Risk Management", in *Risk: Health, Safety, & Environment*, Vol. 39. 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 – see US Office of Management and Budget (2003), *Regulatory Analysis – Circular A-4*. Such requirement has been confirmed in the recent revision of the Circular. The OECD has included the concept of 'risk-risk tradeoffs' as a key regulatory impact to be assessed in its *Recommendation of the Council on Regulatory Policy and Governance* in 2012. The 2023 OECD Report on *Understanding and Applying the Precautionary Principle in the Energy Transition* reaffirms the pivotal role played by risk-risk considerations in the management of risks.

- **Loss of technology pathways**, based on existing knowledge and safe use, that offer opportunities for the incremental development of safer and more sustainable processes, substances and products.

5.2.2. Loss of Critical Technologies needed for the Green Transition and Strategic Resilience

Without reform, the adoption of NRPs by the EU threatens the continued availability of many of the material technologies needed to achieve its ambitious political and social goals. A number of factors contribute to this, including:

- **Loss of the safe use** concept will, if implemented, limit access to some of the most important material technologies;

- Use of risk management mechanisms that **stigmatise material technologies** will reduce investment, trigger reduced demand from downstream users and limit innovation;

- **Groupings** based on unscientific criteria and used to support widespread bans or restrictions, will **remove access to important material technologies that are safe to use**, closing down innovation pathways for producers and users. They will also undermine the operating economics of producers, triggering shifts in investment patterns, making allocation of capital more difficult to justify and creating barriers to reindustrialisation;

- **Erosion of scientific integrity** in implementation processes will create regulatory unpredictability and divert innovative resources away from exploiting the properties of material technologies for safer and more sustainable outcomes; and

- Application of **poorly designed sustainability criteria** and requirements may well **ossify technological developments** rather than stimulating innovation,

5.2.3. 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.[46]

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;
- **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;

46 See ERIF Highlights Note 18 Allocation of Capital, Better Regulation and the Delivery of the Green Deal, 2022.

- **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;

- **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.

5.2.4. Diversion of Resources away from Investment in 'Safer and more Sustainable' Technologies

For the EU to achieve its goals of a green transition, the private sector must retain assets in the EU, shift economic activity away from other jurisdictions and into the EU, and invest in safer and more sustainable processes, substance and products. This will require a massive programme of investment.

The amount of capital available for this will be reduced, and the willingness to invest in the EU diminished, if resources are diverted away from strategic investments into complying with new, untested and disproportionate regulatory requirements, in order to keep existing products on the market or to retain existing functionality. Companies do not, in general, allocate additional resources to comply with new regulatory requirements. To the contrary, funds are diverted away from more productive sources. This is a major opportunity cost of regulatory decision-making (**Exhibit 21**).

EXHIBIT 21

DEFENSIVE R&D AND DIVERSION OF RESOURCES

'Defensive R&D' occurs when scarce resources must be disproportionately diverted, for regulatory reasons, into the defence of existing products or processes rather than into investment in new ideas. It encompasses the application of new regulatory requirements to existing products, substances or technologies, as well as the reformulation of existing products to retain efficacy and performance as a result of regulatory-induced changes.

When faced with these requirements, companies tend to not allocate additional ('new') resources to innovation. There are, therefore, clear opportunity costs of any regulatory decision that creates Defensive R&D for companies. (The budget for research is only spent once.)

Defensive R&D is not a new phenomenon. It is a defining characteristic of the traditional approach to managing risk. Protections are up-dated, requiring additional testing and reformulations, as scientific knowledge and technology progresses. Meeting these requirements is one of the mandatory costs of doing business in developed markets. Indeed, properly designed measures, based on high quality science and likelihood of harm, can strengthen market confidence and create incentives to innovate.

In contrast, poorly designed risk management measures that create disproportionate levels of Defensive R&D have a significant negative impact on citizens, as well as on the scale and nature of innovation and utilisation of technologies:

- **Access to established technologies is lost** – this is a major problem for downstream value chains in general and SMEs in particular, which rely upon ideas embedded in upstream technologies;

- **Loss of financial resources from established substances and products** – this occurs due to loss of access to upstream technologies, leading to higher operating costs and lower margins;

- **Reduction in product availability** – this occurs due to the high cost, relative to margins, of undertaking Defensive R&D;
- **Creation of barriers to entry and competition** – SMEs are often unable to finance the costs of product defence, reducing competition, dynamism and innovation;
- **Diversion of resources away from new ideas** and towards retaining existing products or maintaining efficacy and product performance – this is a major opportunity cost;
- **Retention of old technologies** or limited investment in marginal improvements – this occurs due to the weakening of incentives, including loss of access to technologies and retained earnings;
- **Less investment is available for the development of safer or more sustainable substitutes**;
- **Reduced attractiveness for capital allocation**;
- **Loss of benefits for citizens** – such as less choice, less innovation and less competitive intensity; and
- **Reduced standards of protection for citizens and nature** – due to reduced availability of substances and products that mitigate risks.

In a number of sectors, such as biocides, veterinary medicines, crop protection, agricultural machinery and nickel metallic technologies, levels of Defensive R&D in the EU are significantly higher than those in other jurisdictions.

Source: ERIF[47]

47 See ERF Highlights Note *Defensive R&D and Innovation*, 2016.

One of the most damaging characteristics of the NRPs proposed by the EU is the significant diversion of resources away from investment in developing safer and more sustainable activities. There are a number of reasons for this, including:

- **Major investments in Defensive R&D will be required to comply with new requirements** such as Mixture Assessment Factors (MAFs), new hazard classes, EU-specific reinterpretation of guidance for metals and persistence, and expansion of the scope of risk management regulation (polymers, small volume substances), as well as expenditures required to apply for derogations after the application of widespread bans based on intrinsic properties;

- **Downstream users of technologies, including formulator industries, high-tech biological and chemical sectors and high-tech assembly sectors, will be forced to reformulate products,** if upstream substances, possessing important properties and safe to use, are banned or restricted. Moreover, they may focus expenditure on restoring existing efficacy rather than new developing new properties; and

- **Over precautionary and disproportionate limits on environmental emissions and workplace exposures, divert resources away from investment in greater operating efficiency.** This in turn reduces the capacity to enhance productivity, competitiveness and resilience, and limits investment in safer and more sustainable operating processes. In addition, relative plant economics in the EU are worsened, making allocation of capital more difficult to justify.

5.2.5. Reduced Incentives to Innovate

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 (**Exhibit 22**).

EXHIBIT 22

FRAMEWORK CONDITIONS AND INNOVATION

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, including 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 developed, open economies. 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.

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 'Framework Conditions' are critical, and governments have a role to play.

Framework 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;[48]

- **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 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.

Increasingly, access to a highly developed digital infrastructure also forms part of the Framework Conditions for innovation in mature economies.

Source: ERIF[49]

The framework conditions for innovation at EU-level exhibit strengths and weaknesses. The scale of the Single Market is a powerful incentive, and the EU's large companies and world-

48 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.

49 See ERIF Monograph *Fostering Innovation – Better Management of Risk*, 2015; ERF Highlights Note *Risk Regulation and Innovation*, 2016.

class science base are capable of providing critical inputs of knowledge and human capital. In contrast, there are also major weaknesses, including the EU's regulatory framework.

The proposed novel risk management approach will exacerbate these failings. It 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 safe to use;

- **'Competitive intensity', a major driver of innovative activity in open societies, will be undermined**[50] – 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

50 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.

requirements (including multiple non-toxic criteria for market access, loss of scientific integrity and safe use, MAFs 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; and

- **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.

5.2.6. Structural Damage to the Eco-system of SMEs

Small and Medium-sized Enterprises (SMEs) are the backbone of the EU's economy. Most private sector jobs are provided by SMEs. They are drivers of competitive intensity, one of the most important sources of productivity growth and hence improvements in living standards and prosperity. Many SMEs are also highly innovative or providers of critical inputs, such as surface engineering, to larger companies (see example below), supporting innovation and operating efficiency (**Exhibit 23**).

EXHIBIT 23
SMES – IMPORTANCE AND FRAGILITY

Small and Medium-Sized Enterprises (SMEs) are a critical part of the eco-system of a modern economy. Whilst global companies are responsible for the vast majority of investment in R&D and play a major role in disseminating good managerial and operating practices, SMEs stimulate dynamism, flexibility, innovation, market segmentation and competition, as well as providing high value services and products to larger companies as part of complex supply chains.

Indeed, in successful economies, adaptive and fast moving SMEs often provide larger companies with new ideas and technologies, contributing to overall competitiveness.

SME's, however, face structural challenges. They are small in scale, making it difficult to absorb major exogenous shocks, including new regulatory requirements. They lack access to public capital markets, depending on retained earnings, short-term bank borrowings and supplier credit for funding requirements. This makes it difficult to find additional resources to adapt to regulatory requirements or restrictions. They also lack managerial and technical 'depth', often relying on a very small cohort of managers (often restricted to the entrepreneur or general manager) to direct and undertake critical activities. Diversion of these scarce resources towards responding to regulatory impacts, erodes competitiveness and makes it more difficult to adopt safer and more sustainable products and processes. Overall, SMEs are 'fragile'. Their capacity to innovate, to operate efficiently and to adapt to change, is highly vulnerable to regulatory requirements that create Defensive R&D, restrict inputs or remove market applications.

A significant part of the **Adhesives and Sealants** sector, a group of platform technologies supporting major downstream applications in sectors such as automotive, packaging and building and construction, is dominated by SMEs. The overall sector is highly innovative, investing more than 10% of turnover in innovation, supplying 15,000 standard formulations and a further 10,000 customised ones. SMEs contribute nearly 20% of the turnover of the sector. They focus on specific markets, technologies and segments. They are often highly cost competitive and innovative, stimulating competitive intensity and dynamism. For some highly specialised applications, SMEs provide very high technology solutions for users. They form part of an eco-system of specialist suppliers that support the material economy in the EU and enhance its productivity and capacity to innovate.

The **Surface Engineering** sector provides a similar role for producers of components across all parts of the material economy.

Coatings, many of which use metallic technologies, are added to components by a network of small specialist and highly expert service providers. Coatings deliver properties of durability, appearance, corrosion resistance, and complex engineering functionality. Indeed, almost all components require some form of coating. For example, a modern motor vehicle will contain more than 3,000 plated parts. The surface engineering sector serves a number of downstream industries, most prominently automotive, consumer durables, general engineering, aerospace and medical devices. Surface engineering is already widely used to support the generation of renewable energy, protecting blades and axles within wind turbines from wear and corrosion. Access to a vibrant and innovative surface coating sector is, therefore, a pre-condition for the green transition and greater strategic resilience. Almost all suppliers of surface engineering are SMEs. A typical business is a private, family-owned company with 30-40 employees, located on a single site and close to its customers and generating sales from its services of about Euro 3 million per year. It is also highly innovative, spending 15-20% of turnover on innovation.

Source: ERIF

SMEs are a critical part of the eco-system of the EU's economy. Strengthening their competitiveness is a pre-condition for the delivery of the Green Deal and achieving greater strategic resilience. **Most SMEs have, however, structural weaknesses, which may not allow them to withstand the cumulative regulatory challenges posed by the EU's proposed novel approach.** They lack the financial, technical and managerial capacity to absorb the simultaneous requirements of the EU's NRPs. Over time, this may lead to a diminution in competitiveness and a loss of dynamism, damaging the structure of the EU's economic eco-system. Major problems include:

- **Structural inability to absorb regulatory changes** – the scale, pace and nature of regulatory change needed to implement the EU's NRPs, may be beyond the capacity of many SMEs to absorb without significant economic damage. Too many new measures exhibit characteristics of poor design, inadequate coherence and a lack of workability;

- **Cumulative regulatory impacts** – new requirements interact with extensive existing regulatory requirements creating a cumulative effect. This creates additional opportunity costs and further reduces incentives to invest in innovation and to allocate capital to the EU. This does not appear to have been considered by regulators but has a critical impact on the competitiveness of many SMEs;

- **Diversion of resources** – extensive diversion of resources into Defensive R&D, reformulation and meeting disproportionate emissions and occupational exposure limits, dramatically reduces the availability of retained earnings, the primary source of capital for innovation It also diminishes operating efficiency, further eroding capital for investment in enhanced competitiveness and threatening business continuity; and

- **Loss of critical inputs and markets** – widespread restrictions and bans on substances, based on intrinsic properties and setting aside safe use, remove access to critical upstream technologies, thereby limiting innovation and forcing diversion of resources into reformulation This also reduces revenues and margins, such that fixed costs are unrecovered and business continuity is challenged.

5.2.7. Erosion of Competitiveness of Formulator Industries

Formulator industries are motors of innovation, supporting productivity, delivering product performance and satisfying complex functional and psychological needs in major downstream value chains. They bring together upstream and other speciality technologies, combine them with their own unique insights, market understanding and scientific investments, and create complex products to meet the needs of a wide range of consumer and business-to-business markets. They exploit many of the complex properties of material technologies, and include sectors such as adhesives and solvents, personal care, household care, cosmetics, professional cleaning, and hygiene and fragrances

Because of their scale and the impact of their investments and products on the performance of large parts of the EU's economy, including critical strategic sectors such as aerospace and medical devices, the competitiveness of the formulator sectors is of critical importance for strategic resilience (**Exhibit 24**).

EXHIBIT 24
FORMULATOR INDUSTRIES AND COMPETITIVENESS

Formulator industries and their specialist suppliers form a major, and often overlooked, part of the EU's economic eco-system. They support very large downstream value chains, encompassing business-to-consumer and business-to-business applications. They are major innovators, competing to offer improvements in efficacy and customer satisfaction, along with safer and more sustainable products. Ensuring the continued competitiveness of the EU's formulator industries is one of the pre-conditions for the delivery of the political goals of a green transition and greater strategic resilience.

The Household Care and Professional Cleaning and Hygiene industry is an example of a major formulator industry. For consumers, the industry focuses on laundry care, hand and automatic dish wash, surface cleaners and air care. These complex products touch the lives of every European, every day. In the home, they meet, at low costs, needs for protection from disease and infection, for comfort, appearance and pleasure, for longer-lasting consumer durable and for less onerous lifestyles. Indirectly, they benefit Europeans extensively through the provision of complex cleaning and hygiene products, along with technical advice and equipment, to commercial and industrial customers. As a result, food and drink is safer and cheaper; offices, factories and schools are cleaner and more pleasant place to work; hospitals pose a lower risk of infection to patients; and enjoyment of hospitality facilities is greatly enhanced and safer.

Overall, the technologies and products of the Household Care and Professional Cleaning and Hygiene industry support a value chain that generates Gross Value Added (GVA) of approximately Euro 25 Billion per year and, directly and indirectly, more than 360,000 jobs in Europe alone. In addition, the professional cleaning and hygiene technologies supplied to business users enhance the productivity of a substantial part of the EU's economy.

Overall, the productivity of more than Euro 600 billion of the EU's private sector GVA, supporting over 19 million direct jobs, is significantly enhanced by the products, services and equipment supplied by the industry. The most important sectors affected are food and drink processing, pharmaceuticals, hospitality and contract cleaning.

The Fragrance industry is an important specialist supplier to a number of the EU's major formulator industries, including Household Care, Professional Cleaning and Hygiene, Personal Care and Fine Fragrances. Its complex blends are an essential part of our lives, delivering functional and emotional benefits, such as masking the smell of malodours, helping consumers' adhere to hygiene habits and adding pleasant smells to enhance our well-being and sense of cleanliness. Increasingly they also provide an important means of differentiation, product performance and enhanced consumer satisfaction. Supplying up to 60,000 complex blends that draw on a palette of almost 3,000 ingredients, the fragrance industry has become a "motor of innovation" supporting the competitiveness of its downstream users. To sustain this, the industry invests 8% of its turnover in innovation, including significant expenditure on R&D. Moreover, the industry has made major commitments to become more sustainable, responding to the demands of its customers and shifts in social attitudes. Initiatives include a joint Sustainability Charter; shift in inputs towards renewable carbon, renewable feedstock and bio-inspired ingredients; and support for sustainable production of ingredients.

Sources: ERIF, European Commission[51]; The Huggard Consulting Group[52]

Without significant reform, the application of NRPs for the management of risk may significantly erode the competitiveness of the EU's formulator industries, creating obstacles to achieving the green transition and greater strategic resilience. Specific concerns include:

51 See RPA/Mayer Brown (2018), *Report: European Commission Support for the Evaluation EC 648/2004, Detergents Regulation.*

52 See The Huggard Consulting Group (2016), *The Household Care and Professional Cleaning and Hygiene Products Industry – A Socio-Economic Analysis.*

- **Negative impacts on demand conditions** – weakening of support for scientific integrity, including in the governance of expert scientific committees, along with greater emphasis on novel hazard classes, intrinsic properties and stigmatisation, may erode trust in regulatory decision-making and undermine consumer confidence;

- **Less investment in new ideas and greater emphasis on retaining existing product performance** – removal of the concept of safe use of substances will reduce the available palette of technologies, triggering reformulation, Defensive R&D, diversion of resources, loss of efficacy, reduced margins and further undermining consumer confidence in regulatory decision-making.

- **Value destruction, loss of consumer welfare and potential loss of public consent** – widespread bans and restrictions on the use of upstream technologies, based on intrinsic properties, unscientific groupings and without regard to established safe use, will further restrict the available palette of materials, with negative impacts on Defensive R&D, reformulation and innovation. In some instances, such bans or restrictions may eliminate entire product categories; and

- **Net risk to health and the environment may increase** – there are likely to be behavioural responses to the loss of valued benefits, some of which may increase net risks. Complex, and often hidden, properties of 'Controlled Toxicity' and 'Controlled Persistence' may also be lost, directly reducing the level of protection of man and nature.

5.2.8. Destruction of Value for Major Industries

Delivery on the Green Deal depends also upon sustaining, and increasing investment in the EU by both major processing sectors (i.e. chemicals and metals) and high-tech sectors, including human and animal pharmaceuticals, medical technology and aerospace. It also requires innovation in technologies, products and operating processes to enhance competitiveness, to justify allocation of capital, and to improve sustainability (**Exhibit 25**).

EXHIBIT 25

CAPITAL INTENSIVE PLANTS AND REGULATORY IMPACTS

Allocation of capital to upstream process industries, such as metals and chemicals, is critical for the delivery of the Green Deal and for greater strategic resilience. New capital is required to deliver more sustainable process technologies and to re-shore into the EU processing of core materials required for downstream value chains, such as aerospace, semi-conductors, medical technology, automotive assembly and defence.

Recognising the structural characteristics of major upstream processing facilities is therefore vital. Specifically:

- Facilities are very large scale and integrate different processing activities and products on the same site – business streams, producing different product ranges or technologies, tend not to be easily separable;
- Multiple applications and downstream customers are supplied from the same group of integrated processing activities;
- Facilities are highly capital intensive – the gross current replacement cost of fixed assets can be as high as 90-100% of the value of sales;
- Fixed costs, including fixed operating costs, financing charges and the costs of regular up-grading of plant and equipment to maintain operating efficiency, are likely to be 40-50% of sales revenue, reflecting the capital intensive nature of the facility;
- Capital returns are the ultimate determinant of continued investment in a facility and these are highly vulnerable to shortfalls in sales volumes. For example, a shortfall in output of 25% would lead to a 60% reduction in capital returns for an archetype, highly efficient, large-scale speciality metals processing facility;

- Loss of sales volumes, due to market or regulatory factors, does not lead to any significant reduction in fixed costs, particularly costs of financing and maintaining operating efficiency;

- Failure to recover financing costs leads to an erosion in business value and is assessed annually by investors using modern performance measurement techniques, exposing companies to pressures from capital markets; and

- Global companies operate most upstream processing facilities. They 'benchmark' facility performance against similar facilities in other jurisdictions and recognise that facilities must achieve after-tax risk-adjusted costs of capital determined by global capital markets

Whilst these challenges are common to facilities in all jurisdictions, those located in the EU face additional challenges. Relative energy costs are higher, diminishing gross margins and undermining returns. There are also major regulatory impacts. Emission and exposure standards have on many occasions been set without recognising diminishing social returns and failing to consider analyses of cost effectiveness. There is, in many cases, an exponential cost of seeking abatement to zero but with few, if any, benefits. Finally, the use of NRPs to manage risk, may lead to the loss of significant sales volumes and subsequent destruction of value. If sales are lost due to regulatory interventions, fixed costs remain.

Overall, these challenges in the EU make it more difficult to justify allocation of capital. To the contrary, they create incentives to extract the value of historic investments, to run businesses for cash and to retain old technologies. Potentially, there is less investment in newer, more sustainable processes, less re-shoring, and, eventually, closure of major facilities.

Source: ERIF

The competitiveness of EU-based process and high-tech industries may be significantly threatened by the novel approach to risk management. It may be

more difficult for these sectors to allocate additional capital to the EU, beyond that needed to maintain historic activity, and potentially not even for this purpose. This will diminish strategic resilience and make it harder for the EU to achieve the goals of the Green Deal. Problems include:

- **EU plants may become uneconomic in absolute terms as well as by comparison with similar facilities elsewhere** – loss of downstream applications, revenues and margins, due to widespread bans and restrictions based on intrinsic properties, undermines operating efficiency and threatens the continued viability of capital-intensive processing industries. There may be an inability to recover fixed costs, leading to operating losses and value destruction;

- **Obstacles to investment in new technologies are likely to make it difficult to justify trying to create new sources of value and hence replace losses** – these obstacles include widespread bans based on unscientific grouping and intrinsic properties, the need to meet existing scale and extent of toxicological knowledge so as to demonstrate safety and protect reputation, along with the cost and unpredictability of new requirements;

- **Widespread bans or restrictions on the use of specific substances, without relying on existing vertical legislative framework, safe use or exposures, may lead to the loss of critical technologies used in high-tech sectors** – potential impacts could include elimination of product categories, loss of product efficacy and increases in net risk, as well as closures of R&D and production facilities due to their inability to meet global standards of safe operation; and

- **Property rights are likely to be lost or weakened** – reliance on time limited derogations for continued or future market participation makes property rights dependent on administrative discretion rather than law. Weakened property rights and loss of protection of intellectual property makes it much more difficult to justify allocating capital to the EU or to place new and advanced products on the EU market.

5.3. Overall Assessment – Costs, Benefits and Consequences

To date, there is little robust evidence of likely substantive benefits from the implementation of the EU's NRPs for the management of risk. 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[53] suggest that using it 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.

53 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.

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.

In contrast, potential costs may well be significant, extensive and serious. A further problem is that the EU's approach to the regulation of the development and management of technology is diverging from global norms.

In this context, it will be increasingly difficult to justify the allocation of capital to the EU, beyond the need to sustain productive capacity. Over time, there is very likely to be a progressive fall in the level of resources committed to the EU.

At the time of writing, and assuming that the EU's NRPs are implemented without significant amendment, the potential benefits do not appear to justify the likely costs. Indeed, without change there may well be significant negative unintended consequences, leading over time to regulatory failure (**Exhibit 26**).

EXHIBIT 26

NOVEL REGULATORY PHILOSOPHIES – NEGATIVE UNINTENDED CONSEQUENCES

- **Slower than planned and less extensive attainment of the specific goals of green transition and greater strategic resilience.**
- **Slower technological progress and less investment in safer and more sustainable technologies, substances and products** in the EU than would otherwise have occurred.
- **Distortion of economic activity** favouring retention of old technology, extraction of liquid resources from existing productive assets and pursuit of rent seeking, rather than economic transformation.
- **Possible increase in net risk to health and the environment** due to loss of safe use and risk-risk outcomes.

- **Further weakening of competitiveness of the EU**, because a major deterioration of the regulatory framework, due to the adoption of NRPs, interacts with other structural weaknesses, including relative energy costs, lower levels of R&D and capital market failings. Over time, this may make it even more difficult to allocate capital to the EU and may potentially trigger increased deindustrialisation.

- **Challenges to existing levels of prosperity** due to loss of productive capacity, without replacement by new, more sustainable activity, leading to economic disruption, loss of valued benefits, job losses, adjustment costs and health-health outcomes. (It is an accepted assumption of the EU's Green Deal that existing technologies must be removed through a series of 'negative' decisions' and then replaced by new, safer ones. However, 'positive' decisions do not follow automatically – real world experience suggests they are separate and may not occur.)

- **Threats to consent from citizens for the continued pursuit of ambitious policy goals** because of the potential lessening of protection of health and the environment, negative distributional effects, loss of valued benefits, loss of jobs, higher costs, less choice and economic disruption.

Source: ERIF

6. Conclusions

The EU's Green Deal is by far the most ambitious endeavour taken by political leaders in a generation. It aims to create a greener and more strategically resilient economy in 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 political 'ends', EU policy-makers have chosen radical and equally ambitious policy 'means'. Central to these is the proposed adoption of NRPs for the management of risk and hence for the development and use of material technologies throughout the European economy.

However, this new approach to the management of risk is 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 to a major missed opportunity to achieve fundamental change and potentially regulatory failure.

In part, this situation is the result of evident failings in the way in which NRPs have been developed and implemented.

Too many changes are being attempted, too quickly, and without proper scrutiny. There appears to be only a partial understanding of the functioning, complexity and scale of modern economies. The importance of safe use of technologies for innovation, safety and prosperity appears to be insufficiently understood. Inadequate attention has been paid to the potential dynamic impacts of regulatory interventions. This has resulted in initiatives that tend to lack coherence, be disproportionate, and to over-estimate the capacity and competence of the EU's Administrative State. The cumulative impacts of regulatory requirements on businesses of all sizes – but particularly SMEs – have not been rigorously considered. Finally, there has been insufficient recognition that the EU competes for the allocation of capital with other jurisdictions that use more traditional regulatory frameworks.

Underlying these failings are, however, three more complex factors. Better Regulation principles and tools have not been fully utilised. There has been

insufficient involvement by parts of the business community in supporting the shift in social and political objectives. But most importantly, the new approach has emerged without a major public debate.

The Better Regulation strategy, one of the core strengths of the EU decision-making system, has been applied unsystematically and inconsistently. The development of policies and legislative proposals have not benefitted from systematic robust scrutiny. There has been a lack of rigorous challenge of intervention logic, claimed benefits and idealistic assumptions about behavioural change, technology availability and societal preferences. In too many instances, there has been a failure to apply proportionality and risk-benefit considerations when assessing possible interventions. The importance of policy coherence and understanding dynamic impacts has been largely overlooked.

The process of adopting NRPs has highlighted further structural weaknesses in the EU's Better Regulation strategy. Delegated Acts, an important regulatory mechanism, are inadequately scrutinised. Policy measures, Commission Communications, substantive guidance and novel risk mitigation measures taken by EU agencies (such as Assessments of Regulatory Needs – ARNs) fall outside the scope of Better Regulation. This is not attributable to one specific institutional actor, though. The EU decision-making system rests on a series of checks and balances, ranging from intra- and inter-service collaboration, the Regulatory Scrutiny Board, inter-institutional oversight, public consultation, scientific review and the interaction with the Member States administrations. The interplay of these processes and channels has not delivered sufficient high quality decision-making. These governance weaknesses reveal the lack of a foundational and generally applicable Law of Administrative Procedures.

A further factor is that parts of the business community have failed to anticipate and engage fully with the changing social and political landscape in Europe. There has been, for example, insufficient investment in regulatory science in some key areas of concern, such as eco-toxicity, persistence and endocrine disrupters. The on-going commitment and scale of investment by industrial sectors in a safer and more sustainable way of doing business, has often been inadequately explained. Many sectors have failed to explain fully the public benefits of their economic activities. There have also been controversies and failures to manage risks adequately. All this has contributed to the

perception, amongst some opinion-formers and policy-makers, that regulatory action is needed to direct economic activity towards socially desirable outcomes.

Business is a critical 'actor' in the regulatory process but has failed to engage consistently in important elements of good regulatory governance. On too many occasions, the business community has interpreted 'Better Regulation' in narrow and partial terms, as a means to achieve de-regulation and relief from 'red tape' for example.

While over-regulation might be of concern in individual instances, Better Regulation is a philosophy of government that provides a way of thinking about making and implementing law that helps governments ensure predictability, avoid regulatory failure, and sustain legitimacy. It recognises that regulation plays a fundamental and needed public interest function and that regulatory quality, rather than quantity, forms an integral part of the enabling framework conditions that foster innovation and contribute to sustainable development, prosperity and security.

More generally and arguably most importantly, the EU's new approach has emerged without a major public debate. This has resulted in policy-makers overlooking key issues that should shape the future management of risk and hence the use and development of material technologies (**Exhibit 27**).

EXHIBIT 27
FUTURE MANAGEMENT OF RISK – KEY ISSUES

- Transition is the route to transformation. It takes time and is unlikely, in the modern world, to be achieved by State direction.
- Capital allocation decisions by the corporate sector will determine the extent to which the EU is able to achieve its ambitious goals. Good policy should be informed by real world evidence of how capital is allocated and how investment decisions are made.
- Policy, laws and regulation based on scientific integrity are a pre-condition for allocation of capital.

- The material economy will not be replaced by dematerialisation or new technologies that do not yet exist in practice or have yet to be proven at scale. Transition, greater resilience and prosperity, will depend upon strengthening the material economy and exploiting its properties, including controlled toxicity and persistence. This can only be achieved by focusing on safety and safe use, determined using likelihood of harm.

- The concept of essentiality and direction of investment through NRPs is not compatible with the norms of a market economy.

- Without proportionality between precaution and risk, the EU is less attractive place for the allocation of capital, investment and innovation.

- Attempting to protect citizens and the natural world by guaranteeing absolute safety from all forms of harm is neither feasible nor desirable. It fails to focus on outcomes. Over time, it leads to an increasing range of economic activities being banned, on weak or subjective grounds, unless officials approve their use. This constrains freedoms and undermines consent.

- Retention of the consent of citizens is the critical precondition for achieving economic and social transformation. Without major reform, NRPs erode the foundations of prosperity, diminish freedoms and choice and make safety a secondary consideration. Indeed, protection may be reduced and net risk increased.

Source: ERIF

A structured public debate must also focus on the potential impact of the NRPs on prosperity. This must be maintained to counter threats from authoritarian regimes, crises in living costs and energy availability. To protect prosperity, transition must be separated from transformation; 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.

Major reforms are needed to avoid potential negative outcomes and indeed to seize the opportunity offered by the Green Deal to radically develop the EU's economy and to make it more sustainable and strategically resilient. This opportunity must not be missed.

7. Recommendations

Achieving the goals of the Green Transition and greater Strategic Resilience is of critical importance to the EU and its citizens. They must be achieved. To that end, regulatory philosophies for the management of risk must support and enable rather than impede the transition of the EU's economy.

Better Regulation, revised and improved, has a critical role to play in reforming the design and implementation of risk management philosophies. Used well, it facilitates scrutiny, provides transparency, identifies trade-offs and lack of coherence, and facilitates evidence, understanding and application of proportionality.

Recent developments are encouraging. The European Commission continues to recognise the importance of reforming Better Regulation, if regulatory failure is to be avoided. In response to the Conclusions of the EU Council in early 2023, and aligning with the prioritisation of the long-term competitiveness of Europe promoted by the Swedish EU Council Presidency,[54] it has, for example, strengthened the role of the Regulatory Scrutiny Board and established the requirement of applying a systematic 'Competitiveness Test' to future initiatives.[55] It has also committed to better assessing the cumulative impacts of different policy measures at the EU level.[56] These adjustments do not, however, go far enough.

Based on the findings and conclusions of the research carried out by ERIF, a systematic programme of reform, designed to achieve the EU's political goals and avoid regulatory failure, should focus on five themes:

- Immediately address negative consequences of current initiatives (7.1.);
- Strengthen governance of the regulatory process (section 7.2.);
- Reinforce confidence in scientific integrity in decision-making (7.3.);
- Strengthen conditions for the allocation of capital (7.4.); and

54 See Conclusions of the Special meeting of the European Council of 9 February 2023 (EUCO 1/23); and the results of the Competitiveness Council meetings of February and March 2023, respectively.

55 See the Commission President's statement made at the Plenary session of the European Parliament in October 2022.

56 See European Commission (2023), *Communication on Long-term competitiveness of the EU: looking beyond 2030*, COM(2023) 168 final.

- Build trust, knowledge and understanding of the role of investment (7.5.).

Political will is the foundation on which all reform rests. Recognising this, the structure of recommendations encompasses changes in political commitment, the legislative framework, the institutional architecture and policies and guidelines. The recommendations seek to achieve change with complex organisations and recognise that this takes time to develop, accept and implement. They also include changes designed to reform current concerns as well as ideas for more radical shifts in policy and governance.

7.1. Immediately Address Negative Consequences of Current Initiatives

These measures are targeted at the most important novel regulatory initiatives that are currently being designed or implemented, including essentiality, persistence and sustainability. The measures proposed below reflect widespread concern at the potential negative impacts of the new approach being adopted. They should be implemented urgently.

7.1.1. EU Institutions – Public Debate and Policy Review

Recommendation 1: 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.[57]

57 **High-Level Policy Review** – issues to be considered in the policy review should include: Safety and likelihood of harm; Protection of safe use; Trade-offs – risk-benefit, risk-risk; Harmonisation with global rules, standards and norms; Proportionality (review issues such as scope of application to polymers and the use of widespread restrictions); Protection of primacy of existing 'vertical' risk management frameworks; Scientific evidence to support proposals (such as Priority Setting, Targeting of Interventions, MAFs, and Groupings); Scientific processes for implementation (Groupings); Transparency of implementation processes and decision-making; Feasibility of implementation (weaknesses of the EU's Administrative State); Implementation processes (derogations, property rights and the rule of law); Use of novel risk management mechanisms; Limitations, including legal exemptions, on widespread bans based on intrinsic properties (scientific evidence, proportionality, concentration limit cut-offs, safe use, existing vertical legislation); Protection of property rights (retain existing protections based on vertical legislation); and Dynamic impacts (such as impacts on SMEs, Defensive R&D, incentives to innovate, value destruction, systemic uncertainty and allocation of capital).

7.1.2. *European Commission – Policy Review of the Essential Use Concept*

Recommendation 2: The European Commission should set out a **clear policy framework for the proposed use of tests of 'essentiality' for the management of technologies**.[58]

7.1.3. *European Commission – Policy Review of Sustainability by Design*

Recommendation 3: 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.[59]

58 **Essential Use Concept** – the framework for the use of tests of 'essentiality' should set out the following commitments: All new proposals that seek to implement tests of 'essentiality', non-essentiality', 'necessity' or equivalent concepts for the management of technologies, should be made using formal legislative procedures. They should not be introduced through executive powers, by means of Delegated Acts or equivalent regulatory mechanisms, or substantive guidance; A definition of 'essentiality' must be developed that recognises the complexity of user needs. This definition should be reviewed rigorously using Better Regulation principles and guidelines; The criteria for issuing derogations must be set out clearly, along with the legal basis and legal certainty provided by such decisions; Tests of 'essentiality' should only be applied at the end of application-specific risk analysis processes. They should not precede scientific assessments of the likelihood of harm posed by specific applications of technologies. This reflects their historic use as a rationale for allowing applications to remain on the market, when there are concerns about the level of risk but no viable alternatives, and continued use is needed to deliver important benefits to users. In these circumstances the use of 'essentiality' should form part of the assessment of risk management options for specific applications, most likely within the assessment of socio-economic factors; Implementation should aim to minimise negative consequences including regulatory uncertainty; to strengthen incentives to innovate and to allocate capital to the EU; and to support the achievement of wider EU policy goals, including the EU Green Deal; The implementation framework must recognise explicitly the impact of the proposals on the capacity of the EU Administrative State, including impacts on the work of EU risk assessment agencies; and A clear process for determining 'essentiality' must be defined, including providing appropriate appeals and redress mechanisms.

59 **Safe and Sustainable by Design Framework** – the resulting policy framework should set out the following commitments: It will be applied 'vertically', i.e. exclusively with reference to specific sectors or product systems, using non-binding guidance. It will not be included in legislation or regulation, directly or indirectly; It will use scientifically established levels of safety of substances or materials, based on likelihood of harm, thereby ensuring safe use of critical technologies; It will seek to avoid a static vision of the present technological frontier, jeopardising potential innovation advances and unknown future benefits; It will be focused on outcome considerations, rather than "inputs" (hazard cut-offs) or "processes", to create incentives for investment in safer and more sustainable end-points; It will make extensive use of risk-benefit trade-off analyses, so as to avoid creating potential risk-risk outcomes and regrettable substitution, or inhibiting incremental improvements; It will be based on, and aligned closely with, global best practices and guidelines; It will limit the use of scoring systems unless focused on specific applications contexts, product categories and value chains – all scoring information will be supported by relevant contextual information; Guidance will meet tests of 'workability' so that it can be understood and used by SMEs; and Guidance will be developed progressively using narrowly defined pilot studies and extensive ex post analysis, benefitting from expert inputs from the concerned stakeholders.

7.1.4. European Commission – Scientific Review, Persistence and Hazard Assessment

Recommendation 4: 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 review should include a detailed assessment of hazard assessments and persistence, and should make separate recommendations for a new approach that is up-to-date and fit for purpose**.

7.2. Strengthen Governance of the Regulatory Process

Structural changes are needed in the governance of the regulatory process, so as to ensure that the principles and processes of Better Regulation are used more effectively and systematically to improve the quality of future interventions. Changes should encompass greater focus on proportionality, stronger legal protections for standards of good administration, improved access to expert advice, and enhanced oversight and widening of the formal scope of Better Regulation.

7.2.1. EU Institutions – Political Commitments at Council-level

Recommendation 5: The Council of the European Ministers should adopt dedicated Conclusions calling for a **more robust and systematic application of the Proportionality Principle**, informed by legal requirements set out in the Treaty and in the jurisprudence of the EU Courts.

7.2.2. *EU Institutions – Law of Administrative Procedures*

Recommendation 6: The EU Legislature should, building on the work of the European Parliament, develop and adopt a comprehensive **Law of Administrative Procedures.**[60] This should embed the principles of good administration into law,[61] strengthen judicial review, provide legally enforceable standards and procedural rights and encompass all significant rule-making and adjudication processes used by the EU Administrative State.[62] It will strengthen accountability and transparency.

7.2.3. *EU Member States – Collaboration with EU Institutions*

Recommendation 7: The EU Member States should fully implement the Council Recommendations of 2016 on the establishment of **National Productivity Boards** and expand upon the mandates of the Boards.[63] The contribution of the National Productivity Boards to the development and assessment of EU policy, legislative and regulatory interventions, should be co-ordinated by the Group of Senior Economists of the European Commission, under the leadership of the Vice-President for Competitiveness (see Recommendations 8 and 19 respectively). Properly implemented, this recommendation will create a network effect between Member States and their EU counterparts. Lessons can be drawn from the network of national competition authorities.

60 A Law of Administrative Procedures (LAP) is an essential institutional feature of modern, democratic and effective governments. It places legally enforceable limits on the way in which governments exercise their administrative powers, particularly the rule-making and enforcement decisions taken by the executive function to implement complex laws. It clarifies and protects the rights of citizens and businesses when governments take actions that affect them directly, establishing clear procedural due process and strengthening judicial review. Most EU Member States have an LAP.

61 Four key principles of good administration: transparency and consistency; public participation; public record; and accountability.

62 See ERF Policy Note 21 *An EU-Level Administrative Procedures Act and the Management of Risk*, 2012; ERF Policy Note 30 *EU Law of Administrative Procedures – The Rationale*, 2014; ERF Highlights Note 05 *EU Law of Administrative Procedures – Meeting the Challenge of Better Regulation*, 2016; and ERF Highlights Note 06 *EU Law of Administrative Procedures – Improving Risk Management, Governance and Innovation*, 2016.

63 **National Productivity Boards** – the Boards should: Develop and provide timely expert evidence to inform national and EU-level policies, notably through own initiative studies and by providing inputs to impact assessments and 'Competitiveness Tests'. This will contribute achieving the EU's political objectives; Promote an exchange of information, expertise and good practice among Member States and between the EU and national governments; Review the effectiveness and proportionality of national policies designed to enhance competitiveness, contributing to ex post evaluation; and Promote the application of the Innovation Principle and Better Regulation strategies at national level.

7.2.4. *European Commission – Group of Senior Economic Advisers*

Recommendation 8: 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 group, drawn from officials of the European Commission and outside experts, should report to the new Vice-President for Competitiveness (see Recommendation 19). Its role will be to support Commission services and endorse assessment of the potential impacts on competitiveness of all significant policy, legislative and regulatory interventions throughout the policy cycle. It will focus on micro-economics with particular reference to investment decision-making by the private sector and the dynamism of SMEs.

7.2.5. *European Commission – Mandate of the RSB*

Recommendation 9: The European Commission should revise the mandate of the Regulatory Scrutiny Board (RSB) so as to strengthen its independence, its expert capacity to review risk management interventions and its powers to reject poor quality proposed interventions.[64]

7.2.6. *European Commission – Proportionality Principle Policy*

Recommendation 10: The European Commission should more fully **define the meaning and usage of the Proportionality Principle**, preferably through a Communication. The Communication should be directly informed by the legal requirements set out in the Treaty and in the jurisprudence of the EU Courts. It should explain how the principle should be used to improve the quality of regulatory decision-making, including implementation measures.

64 **RSB Mandate** – the expansion of the RSB mandate should include the following specific actions: Revise and expand the composition of the RSB, such that there is a majority of independent members. A member of the group of Senior Economic Advisors (see Recommendation 8) and a member of the Office for Scientific Standards in Regulatory Decision-Making (see Recommendation 14) should be appointed to the Board *ex officio*; Provide the RSB with access to independent scientific advice, so that it can oversee the quality of scientific evidence used to justify individual risk management measures; and Require the RSB to assess explicitly all interventions against transparent tests of coherence, feasibility, allocation of capital, innovation and proportionality.

The Communication should include four basic tests:[65] (1) Measures should only target significant, demonstrable problems; (2) Measures should demonstrate that the problem is targeted directly and can achieve a measurable impact; (3) Measures should be least burdensome; and (4) Measures should preferably demonstrate that benefits exceed costs or at least that they justify costs.

7.2.7. *European Commission – Revised Better Regulation Communication*

Recommendation 11: The European Commission should revise its **Communication on Better Regulation** to ensure improved scrutiny of the entire policy cycle and to strengthen the focus of regulators on complex dynamic impacts of interventions.[66]

The European Commission should also develop a number of **new Better Regulation Toolkits** that provide detailed guidance for the application of the tests of proportionality, feasibility, coherence, and allocation of capital. It should also revise the existing Toolkit for innovation, taking into account more explicitly framework conditions and the impact of regulatory interventions.

7.3. Restore Confidence in Scientific Integrity in Decision-Making

Science is fundamental to prosperity and social well-being. Confidence in scientific integrity in the design of policy, and its implementation through legislation and regulation, is a pre-condition both of general public consent and for the allocation of capital to the EU. However, this confidence is in danger of being lost through the increasing adoption of the NRPs for the management of risk. The comprehensive reforms proposed below set out to restore confidence in scientific integrity. They encompass major changes in political

65 See ERF Highlights Note 12 *Proportionality Principle and the Management of Risk*, 2020.

66 **Better Regulation Communication** – Specifically, the revisions should: Expand the scope of the Better Regulation policy to include major policies, strategies, Commission Communications, substantive guidance and novel 'soft law' risk management mechanisms; Require Delegated and Implementing Acts, and equivalent regulatory instruments, to be subject to the fullest possible scrutiny (including extended consultation and impact assessment), whenever they are used to substantively define the meaning and coverage of framework legislation; Establish additional mandatory tests for all interventions. These should consider proportionality, coherence and feasibility, as well as impacts on innovation and allocation of capital; and Require EU Member States to provide expert assessments of the potential national costs and benefits (including distributional impacts and impacts on national competitiveness) of proposed interventions at early stages of the impact assessment process.

commitments and institutional architecture. They also recommend the adoption of new, 'horizontal' policies and guidelines for scientific integrity.

7.3.1. EU Institutions – Political Commitments at Council-Level

Recommendation 12: 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**.

7.3.2. EU Institutions – Non-Food Consumer Safety Agency

Recommendation 13: The EU Legislature should establish a new **Non-Food Consumer Safety Agency**. This will support the existing independent scientific committees and provide, initially, the implementation mechanisms for legislation, for instance, regulating cosmetics and detergents. The agency will provide part of the structure of governance needed to ensure consumer safety. Over time, the agency could expand its activities to support the implementation of other risk management laws that seek primarily to ensure consumer safety for sectors not covered by the existing agencies for medicines (EMA), chemicals (ECHA) and food (EFSA).[67]

7.3.3. European Commission – Office of Scientific Standards

Recommendation 14: The European Commission should adopt a Commission Decision establishing a new **Office for Scientific Standards in Regulatory Decision-Making**. The Office, drawn from officials of the European Commission and independent eminent expert scientists, should report to the Vice-President with responsibility Better Regulation. Its role will be to oversee and support the functioning of the new Independent Appeals Board (see Recommendation 15) and to draw up and enforce the new horizontal policy for Principles and Guidance for Scientific Integrity in Regulatory Decision-making (see Recommendation 17).

67 See ERIF Monograph *Scientific Excellence in Consumer Safety – Insights for the Better Regulation Agenda*, 2022; ERIF Policy Note 24 *Consumer Safety, Good Governance and Scientific Excellence*, 2022; and Berry, C. (2020), "Frameworks for evaluation and integration of data in regulatory evaluations. The need for excellence in regulatory toxicology", in *Toxicology Research and Application*, Vol. 4.

7.3.4. *European Commission – Independent Appeals Board for Scientific Assessments*

Recommendation 15: The European Commission should adopt a Commission Decision establishing a new **Independent Appeals Board for Scientific Assessments**. The Board, which shall be overseen by the new Office for Scientific Standards in Regulatory Decision-Making (see Recommendation 14), will comprise expert and eminent independent scientists. Its task will be to assess significant scientific assessments (including hazard assessments, risk assessments and groupings) where there has been evident failure to respect agreed procedural requirements, or evident substantive failings by other scientific assessment bodies in the preparation of EU risk assessment and risk management decisions. Registrants may file appeals. The Board will have the power to reverse previous scientific opinions, where substantive new scientific evidence has become available.

7.3.5. *European Commission – Network of Independent Scientific Committees*

Recommendation 16: The European Commission should adopt a Commission Decision establishing a new **network of standing independent scientific committees**. These committees should comprise independent eminent scientists. Their governance will be based on the Commission Decisions and Rules of Procedure that currently underpin the functioning of the Scientific Committee for Consumer Safety. The new committees will be structured to focus on highly specific issues such as exposures (emissions or occupational exposures), different hazard classes, groupings and inorganic substances. ECHA Secretariat will support the new independent committees.

7.3.6. *European Commission – Principles and Guidelines for Scientific Integrity in Regulatory Decision-Making*

Recommendation 17: The European Commission should adopt a Commission Decision setting out **principles and guidelines for Scientific Integrity in regulatory decision-making.** These should be based on global best practices. They will be mandatory and 'horizontal' in application. They will set a minimum standard. The new Office of Scientific Standards in Regulatory Decision-Making will oversee their development, implementation and enforcement (see Recommendation 14). They will cover minimum standards for study

quality, assessment, communication to risk managers of opinions and selection of eminent and relevant experts.[68]

7.4. Strengthen Conditions for the Allocation of Capital

A greater focus on competitiveness will strengthen the conditions for the allocation of capital to the EU, so as to deliver the EU's ambitious goals. So far, policy-makers have paid insufficient attention to this issue. These reforms focus on competitiveness. They seek to create the institutional context within which current and future interventions, including NRPs, will be shaped to promote the capacity of the EU's economies to stimulate innovation, improve operating efficiency and facilitate strategic adjustment. To achieve this, the proposed reforms include major changes in political commitments, institutional architecture and technology policy.

7.4.1. EU Institutions – Political Commitments at EU-Level

Recommendation 18: 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**.

7.4.2. European Commission – Vice-President for Competitiveness

Recommendation 19: 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 (see Recommendation 20). It 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. It will work with other Commissioners to support the wider application of the Innovation Principle. It will oversee the work of the new group of Senior Economic Advisors (see Recommendation 8).

68 See ERIF Communication 20 *Principles and Guidelines for Scientific Integrity in Regulatory Studies*, 2021; and Berry, C. (2020), "Frameworks for evaluation and integration of data in regulatory evaluations. The need for excellence in regulatory toxicology", in *Toxicology Research and Application*, Vol. 4.

7.4.3. *European Commission – Innovation Policy*

Recommendation 20: 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.[69] 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.[70]

7.5. Build Trust, Knowledge and Understanding of the Role of Industrial Investment in Implementing the Green Deal and Greater Strategic Resilience

Business is a party to the development of public policy and its effectiveness. It needs to recognise its responsibilities. It has to accept that its activities have not always built confidence. It needs to invest to build trust and knowledge.

7.5.1. *Business Investment in Regulatory Science*

Recommendation 21: Companies and trade associations should commit to further investing in the further development of **regulatory science** in areas of concern to the European Union. This includes eco-toxicology, persistence and intrinsic properties, non-toxic persistence, groupings, endocrine disruption, new approach methods (NAMs), sensitization and exposures. Ideally, new ways of undertaking regulatory science should be used that build trust with regulators and more widely.

69 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.

70 Technology Management and Development Policy – This policy should be based on a set of principles that emphasise the centrality of safe use and safety based on likelihood of harm; of property rights, certainty and predictability; and of outcomes-driven government action; technology neutrality. They should also emphasise the important role played by framework conditions, incentives and market mechanisms (including investment economics considerations and using standards, guidance or self-regulation); 'Safer and More Sustainable' approaches and technological feasibility tests.

7.5.2. *Business Investment in Socio-Economic Analyses*

Recommendation 22: Companies and Trade Associations should commit to further investing in the development of robust and comprehensive **socio-economic analyses (SEAs)**. These explain the complex contribution that industries, their technologies and their value chains make to modern society, including contributions to prosperity, competitiveness, safety, green transition and strategic resilience. SEAs highlight the public benefits of business activity, transparently contributing to public policy debates, informing opinion formers and helping regulators make better, more balanced decisions.

7.5.3. *Business Investment in Communicating Investment Economics and Regulatory Impacts*

Recommendation 23: Companies and Trade Associations should commit to further investing in the **development of communication materials** to communicate the following to opinion-formers and decision-makers:

- Investment decision-making by companies, including allocation of capital decisions and investment economics;
- Dynamic impacts of regulatory decisions and how they affect competitiveness, including allocation of capital, SMEs, incentives to innovate, availability of resources; and
- Substitution, focusing on the time and cost needed to develop new technologies, including barriers to adoption.

7.5.4. *Business Engagement in Multi-Stakeholder Dialogue and Collaboration*

Recommendation 24: Companies and Trade Associations should actively engage in fostering **dialogue and strengthening communication with various stakeholders**, notably at the level of Social Partners. Private sector members of the Fit-For-Future

Platform[71] should promote multi-stakeholder joint initiatives for robust and comprehensive review of the legislative framework affecting innovation, competitiveness and strategic resilience, beyond the assessment of administrative costs.

7.5.5. Business Investment in Regulatory Impact Surveys

Recommendation 25: Business organisations should conduct large-scale surveys of companies, covering all parts of the material economy, to identify and track the **impact of the regulatory framework on competitiveness**. Surveys should look at detailed impacts and their consequences, covering issues such as allocation of capital, innovation, operating efficiency and structural adjustment.

European Regulation and Innovation Forum
July 2023

Richard Meads and Lorenzo Allio, the Rapporteur and the Senior Policy Analyst at the European Regulation and Innovation Forum, wrote this Monograph. 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.

71 The Fit-for-Future Platform is a high-level expert group that helps the Commission in its efforts to simplify EU laws and to reduce related unnecessary costs. These efforts are part of the Regulatory fitness and performance (REFIT) programme. The Platform examines whether existing laws can achieve their objectives efficiently as new challenges, such as digitalisation, are tackled.

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 or contact info@eriforum.eu.

European Regulation and Innovation Forum
Rue de la Loi 227
B-1040, Brussels
Belgium

European Regulation & Innovation Forum

www.eriforum.eu