

NOVEL REGULATORY PHILOSOPHIES – FUTURE DIRECTIONS AND IMPLICATIONS FOR RISK MANAGEMENT

HIGHLIGHTS NOTE 21

- This Highlights Note focuses on the adoption by the EU of a radically new way of managing risk and hence the availability of technologies.
- It shows how a series of interlocking novel regulatory philosophies, to be implemented at scale across the entire material economy, raise significant concerns for the delivery of the European Green Deal and the achievement of greater resilience.

BACKGROUND

Across the OECD area, ‘likelihood of harm’ remains the dominant regulatory philosophy for the management of potential risks to humans and nature posed by the development, production and use of 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 inherently safe. All pose potential threats of harm to man or nature, depending on usage and exposure. Governments have, therefore, sought to manage possible risks by ensuring safety, whilst facilitating ‘safe use’.

This has been the traditional approach to risk management across the OECD area. It rests on the concept of ‘likelihood of harm’. Regulatory decisions are based on an understanding of the intrinsic properties of materials (‘hazards’), their applications, and their specific exposures, using evidence derived from the best available science and assessments by eminent, relevant and independent experts. Mitigation decisions are application-specific, proportionate and informed by an understanding of dynamic impacts, including risk-

benefit and risk-risk tradeoffs (see [ERIF Highlights Note 20 ‘Regulation and the Management of Risk – Likelihood of Harm, Safety and Safe Use’ 2022.](#))

Within this context, 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 tradeoffs explicit; (4) developing incentives to invest in socially desirable outcomes; and (5) using regulation as an ‘enabler’.

There is no evidence of a systemic failure of this traditional approach. On the contrary, the established framework, based on likelihood of harm, has facilitated major social, environmental, economic and governance gains.

For more than twenty years, however, the EU institutions have been moving away from the traditional approach and appear now to be progressively embracing a series of “novel regulatory philosophies” that seek to actively direct the development of technologies and their applications.

EU RISK MANAGEMENT – NEW APPROACH AND NOVEL REGULATORY PHILOSOPHIES

The EU 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 material technologies.

In contrast to other parts of the OECD area, the EU appears to be moving towards a radically different form of risk management, based on a series of novel regulatory philosophies. Regulation becomes a driver and not an enabler. Policy, law, regulation and its implementation are being shaped to direct the development, production and use of technologies, so as to achieve a series of policy objectives. These encompass protection of citizens and nature from all forms of potential ‘harm (‘toxic’ and ‘non-toxic’); alleviation of worries or concerns; insurance against uncertainties; greater sustainability and ecological harmony; and social betterment.

Within this new risk management context, objectives of ‘safety’ and ‘safe use’, based on likelihood of harm, may become of secondary importance.

This new approach to managing risk 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 and change is occurring (‘typology of novel philosophies’). Specifically:

- The progressive ‘evolution’ of the traditional model of risk management;
- The adoption of non-toxic criteria (harms and social goals) for technology management; and
- The ‘upstream’ direction 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. In pharmaceuticals, medical devices, cosmetics, detergents and some industrial chemicals, for example, decisions are primarily based 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. A more 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. Hazard-based laws have been introduced in some domains, most notably biocides and crop protection. There is extensive evidence across several sectors that scientific assessments have become more precautionary and, in some instances, of insufficient quality. Too many risk mitigation measures lack proportionality, failing to fully account for risk-benefit considerations and unintended consequences (including risk-risk tradeoffs) (see [ERF Monograph ‘Risk Management and the EU’s](#)

[Administrative State – Implementing Law through Science, Regulation and Guidance’ 2019.](#))

Proposals set out in new policy initiatives at EU-level, including the Chemicals Sustainability Strategy will accelerate and amplify these trends, if adopted without reform. Key trends include:

- Management of uses and development of material technologies primarily on the basis of their intrinsic properties (rather than likelihood of harm and safe use);
- Interventions seek to avoid all harms (toxicity, as well as social worries and concerns), current uncertainties and future regrets;
- 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 generic mitigation measures – limited consideration of likelihood of harm or safe use of applications;
- Widespread bans, based on intrinsic properties precede granular assessments of applications;
- Changes in governance of independent scientific committees, eroding expertise, lessening understanding of safety and threatening quality of assessments (see [ERIF Policy Note 34 ‘Consumer Safety, Good Governance, and Scientific Excellence’ 2022](#));
- Use of arbitrary and precautionary adjustment factors within scientific assessments of new and existing substances - robust scientific evidence to support this is still lacking;
- 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 tradeoffs.

The evolution of the traditional model, its new priorities, directions and characteristics, interacts with the increased adoption by the EU of non-toxic tests of market access.

NON-TOXIC CRITERIA TO DETERMINE MARKET ACCESS

The traditional model of risk management focuses on protecting 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 tests of 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 nature

of processes or substances used by the private sector ('sustainability').

(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 generic restrictions, entire classes of technologies will 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 be 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 wider theory of 'necessity' that justifies restrictions on market access for all new or existing products unless that can demonstrate that they are needed for "social betterment". (See [ERIF Highlights Note 16 'Essentiality, Better Regulation and Management of Risk from Technologies' 2021.](#))

It is argued, by supporters of this novel concept, that its application will speed up the process of restricting the availability and use of existing hazardous technologies and direct the development of new (safer) ones, thereby stimulating investment in innovation. In turn, this should lead to higher standards of protection. Little evidence, however, has been produced to date to support these claimed benefits. (See [ERIF Highlights Note 19 'Innovation, Essentiality and Better Regulation' 2022.](#))

The effect of the application of the test of 'essentiality' is to restrict the availability and use of existing technologies and to 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 and replace traditional socio-economic assessments.

Although the process of refining the implementation of this new risk management test is incomplete, '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 Green Taxonomy.

(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. This is a long-standing and widely accepted approach.

The rationale for regulating certain properties of persistence is complex. It reflects, in part, evidence of toxic harm for certain classes of hazard. In part, restrictions are mandated even 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. The scope of application 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 and assessment changes 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.

(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 facing governments globally (UN Agenda 2030). There is widespread support amongst citizens and companies of 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.

Within this evolving policy context, 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 envisages extensive change throughout the EU economy, on an enormous scale. 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 sustainability goals.

Although the 'means' by which the EU will deliver its sustainability goals ('ends') are evolving, a number of trends can be identified:

- Development of soft law instruments, such as guidance and platforms to share methodological tools on issues such as safety and sustainability, such as 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;
- 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 tradeoffs 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 novel regulatory philosophies, most notably defining safety on the basis of intrinsic properties, rather than using likelihood of harm, 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.

'UPSTREAM' – DIRECTION OF INVESTMENT

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 in innovation, operating efficiency and markets. This is the 'upstream' dimension of the typology of novel regulatory philosophies being adopted at EU level.

Examples include the EcoDesign for Sustainable Products Regulation and policies, potentially including legislation, to encourage "healthy and sustainable diets".

One of the most important concepts that underpins this new approach to risk and technology management is **'Safe and Sustainable by Design'**. Its ideas are applied to investments in more sustainable products, sourcing, operating processes and target markets.

The origins of the Safe and Sustainable by Design (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 shaped 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, including US Green Chemistry, OECD Guidance, corporate guidelines, financial reporting guidance and the JRC guidance in the EU, 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.

From these initiatives, an overall framework of good practices, set out in guidance, has emerged: **(1)** Share good practices, particularly for SMEs; **(2)** Strengthen 'value drivers' within the private sector, focusing on factors such as reputation, customer preferences, operating efficiency, competitive advantage and reputation management; **(3)** 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"; **(4)** 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; **(5)** Focus on outcomes, incentives and systems rather than direction, products and inputs.

At EU-level, however, the SSbD concept interacts with other novel regulatory philosophies, specifically those set out in the new ERIF typology, giving rise to a series of different characteristics when embedded in legislative and regulatory interventions. These include:

- It is likely to be applied 'horizontally', through framework legislation complemented by specific delegated acts;
- Use of "One size fits all" criteria that might be too generic and do no justice to differences within individual product categories and value chains;
- It may use hazard characteristics (as defined in the revised CLP) 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 based on the essentiality test;
- It may focus on 'negatives' rather than outcomes – bans on inputs, production processes or methods and product categories, instead of safer and more sustainable end-points; and
- It might result in a static vision of the present technological frontier, jeopardising potential innovation advances and unknown future benefits.

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.

NOVEL REGULATORY PHILOSOPHIES – CHARACTERISTICS

The EU's radical new approach to the management of risk, through the adoption of a series of interlocking novel regulatory philosophies, has a number of distinctive features. These include.

- No adequate evidence of benefits to give legitimacy to specific policies or regulatory interventions, with weak intervention logic and assessment of costs and benefits;
- Safety and safe use of technologies, based on likelihood of harm, are secondary considerations;
- Limited focus on the core principles of Better Regulation, including evidence-based decision-making, assessment of costs and benefits and proportionality;
- Marginalisation of toxicological and associated scientific knowledge, and a loss of existing vertical and expert risk assessment, thereby undermining scientific integrity;
- Ambitions of policy and regulatory interventions exceed the capacity of the EU's Administrative State;
- Regulatory interventions drive technological development rather than ensuring safety, facilitating safe use and enabling innovation;
- Interventions focus on inputs and processes rather than outcomes and incentives; and
- Traditional economic norms, based on markets, choices and trust, are replaced by a new economic model characterised by limited competition, rent-seeking, weak property rights and direction of activity by officials.

As yet, there is little evidence to demonstrate that the new approach being adopted by the EU for the management of technologies will deliver sufficient improvements in health, environmental protection, sustainability or resilience to offset the likely costs.

Indeed, the adoption, without major reform, by the EU of novel regulatory philosophies for the management of risk may trigger significant unintended consequences. These may include: **(1)** Diversion of resources away from productive innovation, more sustainable products and processes and improved operating efficiency; **(2)** Loss of technologies vital for innovation, productivity, prosperity, resilience and green transition; **(3)** Impairment of dynamism due to losses of SMEs and obstacles to investment in innovation; and, **(4)** Reduction of existing high levels of protection of people and nature, along with confidence of consumers.

There may also be major disincentives to the allocation of capital to the EU. Business value, derived from existing assets and technologies, may be destroyed, and major obstacles created to investment in new sources of value. Without substantial change, systemic uncertainty will be created due to regulatory unpredictability, administrative discretion and weakening of legal certainty and property rights. (See [ERIF Highlights Note 18 'Allocation of Capital, Better Regulation and the Delivery of the Green Deal' 2022.](#))

ERIF OBSERVATIONS

The EU institutions have set out ambitious policy goals in response to a series of major challenges. **The aims of these policies are widely supported but more attention should be given, from a Better Regulation perspective, to the 'means' proposed by the European Commission to achieve these goals.**

Delivery of these policy goals requires, in particular, the allocation of very large amounts of private sector capital to the EU for major investments in new ideas, innovation and operating processes. One of the most important challenges facing EU-level policy makers is how to ensure that all public policy measures, including risk management, support these wider goals, rather than undermining them.

However, there is growing concern amongst investors about the lack of understanding amongst policy makers of the processes by which business allocate capital and make investment decisions. A focus on coherence in policy and regulatory implementation, together with mapping of the impact and coherence of novel regulatory approaches, and thorough application of Better Regulation principles at every stage of policy making and implementation, could do much to address these concerns and facilitate the investment needed for delivery Europe is in very real danger of shooting itself in the foot on Green Deal delivery. Regulators need to pay much greater attention to how private investors actually make capital allocation and investment decisions in the real economy and to adjust policies accordingly of the EU's ambitious and widely supported goals.

European Regulation and Innovation Forum March 2023

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