



EUROPEAN REGULATION AND INNOVATION FORUM – COMMUNICATION 21

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EXECUTIVE SUMMARY

This Communication by the European Regulation and Innovation Forum (ERIF) is a contribution to the future development of the Better Regulation strategy at the EU level. It builds upon and complements, in part, the ideas developed in the recent European Commission Communication *'Better Regulation – Joining Forces to make better laws'* of April 2021.

The 2021 European Commission Communication is to be welcomed. Not only does it reaffirm the leading position of the European Commission in structuring good regulatory principles and practices in the OECD area. It also recognises the role of regulations within the framework conditions for economic activity; and commits the institution to improved consultation, better ex post evaluation, and to a more transparent dossier of evidence used to support decision-making. These are significant reforms that will further improve the quality of regulatory decision-making at EU-level.

Despite these improvements, more needs to be done if the EU is to make full use of the potential for Better Regulation to help deliver the ambitious social and environmental goals sought by its citizens.

Better Regulation tools offer a critical means of thinking about making and implementing law that helps governments ensure predictability, avoid regulatory failure, and sustain legitimacy and consent. It is at its most relevant for good governance when governments set out to deliver complex and radical policies that require extensive legal and regulatory decision-making. Extensive use of the principles and tools of Better Regulation can help the EU deliver the aims of the European Green Deal.

Building on the new Commission Communication and existing Better Regulation guidelines, this ERIF Communication identifies a series of additional recommendations that will, if adopted, further improve the quality of law-making, and the mechanisms used to implement rules, as well as helping to achieve the social and environmental aspirations of EU citizens, particularly through the European Green Deal. The recommendations reflect the structure of the note, specifically:

Shared regulatory responsibility

- The European Commission should, building on earlier work by the European Parliament, develop and adopt a legislative proposal for a comprehensive Law of Administrative Procedures.
- The European Commission should expand and tailor the scope of the Better Regulation requirements, its Guidelines and Toolbox to encompass all forms of implementation mechanisms, including regulation (through comitology), substantive guidance, and standards. Particular attention should be paid to coherence with other policy objectives, dynamic impacts, scientific evidence, administrative appeals, and risk-risk.

Framework Conditions and Regulation

- The Commission should affirm more explicitly the central role played by innovation in the transition triggered by the Green Deal. Consequently, it should revise the Better Regulation Guidelines to more thoroughly identify the impacts of regulatory processes and decisions on incentives to invest in innovation along value chains.
- The Commission should undertake a series of ex post evaluation and benchmarking exercises to identify time-to-market and Defensive R&D problems and their causes, including an appraisal of the assumptions and models used to design EU legislation and

of the related implementation processes and mechanisms. Based on these reviews, specific reforms should be identified.

Evidence and Regulation

- The Commission should develop and adopt minimum standards for scientific integrity, covering study quality, assessment of studies, risk communication and selection of relevant and eminent experts that all directorates and agencies must respect. These could be set out, for instance, in a new decision.
- The Commission should, as an integral part of its Better Regulation framework, ensure the enforcement of such standards for scientific integrity, as well as the coordination and active promotion of good practices across all EU institutions and bodies – for instance through the Scientific Advisory Mechanism, the Joint Research Centre, and the EU-ANSA network.

Consultation and Transparency

- The Commission should actively promote the organisation of public hearings and other opportunities for interactive debate during the elaboration of regulatory proposals, including implementing measures.
- Commission guidelines for consultation with stakeholders should ensure that evidence from scientific assessments is not included in any single grouping of inputs, and that scientific papers or findings put forward by stakeholders are fully evaluated to ensure integrity and, if necessary, included with appropriate expert comments.

Regulatory Decision-making and Governance

- The Council of the EU Ministers should adopt dedicated Conclusions calling for a more robust and systematic application of the Proportionality Principle.
- The Commission should define the meaning and usage of the Proportionality Principle, possibly in the form of a Communication. The Communication should be informed by 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. The document should also recognise the need to transparently appraise alternatives, risk-risk, and socio-economic impacts when developing risk management decisions, basing estimates of the resulting benefits on the weight-of-evidence.
- A new Toolkit should be developed by the Commission that provides detailed operational guidance for the application of the Proportionality Principle Communication, including methods of complying with core tests of proportionate action. (Blueprints of such tests are presented in this ERIF Communication.)
- Compliance with such core tests of proportionate action should be one of the prominent formal ‘quality’ requirements applied by the Regulatory Scrutiny Board to all measures, including those that implement complex risk management laws.

Regulatory Uncertainty

- A new toolkit is needed to provide detailed guidance for the application of the “do no significant harm” principle to the development of new legislative measures and to the implementation of existing ones. This guidance should recognise explicitly the potential for this new regulatory principle to create systemic uncertainty and demonstrate how this will be avoided.
- The EU institutions should launch a structured and informed society-wide debate on “essentiality” and assessment of the socio-economic benefits of using ‘safety’, ‘risk’, and

'sustainability', rather than 'essentiality', to regulate the use and development of technologies. This will provide a better understanding of the context within which new, untested ideas are being proposed.

Ex Post Evaluation

- The Commission should revise the ex post evaluation guidelines to explicitly identify 'horizontal' issues that may affect incentives to innovate or may create obstacles to the allocation of capital to the EU. It should include implementation processes undertaken by the EU Administrative State. Possible issues could include 'time-to-market', Defensive R&D, access to technologies, as well as underlying regulatory assumptions and modelling.
- The Commission should ensure that the application of new, novel, and untested regulatory principles, most notably 'essentiality' and 'do no significant harm', should be subject to rigorous ex post evaluation.

Regulatory Oversight

- The scope of the RSB review should be broadened to also consider the coherence between regulatory strategies and wider political goals, notably with regard to the identification of all relevant options and their prioritisation.

Foresight

- When expanding its Better Regulation guidelines to include Foresight for policy-making, the Commission should ensure that a clear distinction is drawn between different types of evidence, and the quality standards they must meet, particularly when examining proposed risk management measures.

Innovation

- Requirements to apply the Innovation Principle to all proposed policy, legislative and implementing measures should be strengthened, and new guidance drawn up to ensure that it is used to highlight incentives and obstacles to invest in innovation.

Allocation of Capital

- The Better Regulation guidelines should be expanded to develop an "Allocation of Capital Test". This should be applied to policy and legislative proposals, and could form part of the ex post evaluation programme.

New Technologies

- The Commission should develop a formal policy for the regulation of new technologies. This should be based on global best practices. Better Regulation principles and guidelines should be revised to ensure that the requirements of the policy for new technologies are respected when new legislative proposals are developed.

Human Consequences

- The Commission should strengthen the requirements and methodological guidance for assessing and understanding the dynamic impacts of proposed legislative and implementing measures set out in the Better Regulation guidelines, particularly with regard to distributional impacts on socio-economic and health conditions across Europe.

**European Regulation and Innovation Forum
July 2021**

1. INTRODUCTION

This Communication by the European Regulation and Innovation Forum (ERIF) is a contribution to the future development of the Better Regulation strategy at the EU level. It builds upon and complements, in part, the ideas developed in the recent European Commission Communication 'Better Regulation – Joining Forces to make better laws' of April 2021.

The ERIF Communication highlights ways in which Better Regulation concepts, principles, and tools can be used to further improve the quality of law-making, and the mechanisms used to implement rules, as well as to achieve the social and environmental aspirations of EU citizens, particularly through the European Green Deal. In so doing, the Communication rests on earlier contributions by ERIF, most notably the [detailed response](#)¹ to the European Commission's public consultation in 2018.

This ERIF Communication is structured in three parts:

- Section 2 restates the principal elements of the latest Better Regulation Communication of the European Commission. It provides short comments, highlighting areas of progress, concerns, and related open questions. It also includes ideas for possible improvements.
- Section 3 identifies a number of additional themes (and related recommendations) that are not included in the 2021 Commission Communication, and which could be addressed as the Better Regulation strategy evolves.
- Section 4 sets out brief conclusions.

2. THE 2021 EUROPEAN COMMISSION COMMUNICATION

2.1. Key Themes

Typically issued at the outset of the European Commission's mandate, the Communication on Better Regulation establishes the guiding philosophy for the application of good governance and regulatory practice. It is, in part, a statement of purpose and commitment, establishing what the Better Regulation strategy should achieve and how this will be accomplished. As such, the Communication is a document of considerable political and policy importance.

In its 2021 Communication, the von der Leyen Commission frames the Better Regulation strategy as supporting the recovery from impact of the pandemic, whilst, at the same time, ensuring that legislation is better adapted for tomorrow's needs, most notably the emergence of a greener and more sustainable future. It also seeks to address major shortcomings in the application of the Better Regulation strategy identified by the stock-taking exercise culminating in 2019.

To achieve these aims, the Communication identifies the following priority strands for action:

¹ ERF Communication 19 (2018), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/181108_erf_-_ec_public_consultation_booklet.pdf.

- **More emphasis on a joint legislative endeavour encompassing the EU co-legislators, as well as the Member States** – the European Parliament and Council are urged to meet their commitments in the Inter-institutional Agreement on Law-making; implementation by Member States will be scrutinised more rigorously; and, the importance of inter-institutional responsibility for data collection and scientific evidence will be recognised more widely;
- **Better communication with stakeholders and the general public** – consultation will be made easier through a single “call for evidence” system, with simpler questionnaires and more straightforward web access;
- **Increased transparency** – access to the evidence on which decisions are based will be improved, including opening up scientific evidence to public scrutiny;
- **Further simplification and burden reduction** – the ‘Fit for Future Platform’ replaces its predecessor under the REFIT programme with annual work programmes; the “one-in, one-out” mechanisms will be progressively introduced as a new regulatory instrument so as to quantify the costs of compliance more systematically and transparently, with the aim of better achieving policy objectives;
- **Improved toolkit** – under the sustained supervision of the Regulatory Scrutiny Board, strategic foresight will be further integrated into policy-making, impact assessments, and major evaluations, so as to ‘future-proof’ legislative proposals; impact assessments will focus more on how proposals contribute to the UN SDGs and impact on green, digital, social justice, and gender equality, not least through the “do no significant harm” principle; the SME Test will be applied more systematically and proportionately; greater emphasis will be placed on subsidiarity as well as on evaluating negative unintended consequences; and
- **Better enforcement** – Member States will be encouraged to strengthen enforcement of the implementation of EU legislation to ensure a smooth functioning of the Single Market.

2.2. ERIF Observations

The 2021 Communication is to be welcomed. Not only does it reaffirm the leading position of the European Commission in structuring good regulatory principles and practices in the OECD area. It also recognises the role of regulations within the framework conditions for economic activity; and commits the institution to improved consultation, better ex post evaluation, and to a more transparent dossier of evidence used to support decision-making. These are significant reforms that will further improve the quality of regulatory decision-making at EU-level.

Despite these improvements, the coverage of the Communication also highlights a number of issues and concerns. These include:

- Shared regulatory responsibility (section 2.2.1.)
- Framework conditions and regulation (2.2.2.)
- Evidence and regulation (2.2.3.)
- Consultation and transparency (2.2.4.)
- Regulatory decision-making and governance (2.2.5.)
- Regulatory uncertainty (2.2.6.)

- Ex post evaluation (2.2.7.)
- Regulatory oversight (2.2.8.)
- Foresight (2.2.9.)

2.2.1. Shared Regulatory Responsibility

Whilst the European Parliament and the Council should indeed step up their efforts to concretely and systematically implement Better Regulation principles, the conceptual approach taken by the Communication continues rest on an out-dated vision of how laws are made and implemented at EU-level.

At present, the most important means of implementing EU law in virtually all of the policy domains that lie at the core of the European Green Deal *no longer take place at Member State level but centrally*, through EU agencies and expert groups, ‘comitology’ as well as substantive guidance and standards. This reflects the increased exercise of powers by the executive function that occurs in all major OECD economies. Most commonly, the implementing powers of the state take place within a clear legal framework that embeds the principles of good administration, strengthens judicial review, and provides legally enforceable standards and procedural rights. Such a framework, which is a natural complement to Better Regulation strategies, does not exist at EU-level and good regulatory principles and practices do not systematically apply in the EU’s centralised implementation phase. The Communication crucially fails to consider the importance of this.

The ERIF has addressed this key aspect extensively in a pioneering study on the [EU Administrative State and its implications](#).² The study identified major failings of governance and a mismatch between resources and the scope of responsibilities entrusted to the EU’s Administrative State. These contribute to a significant risk of implementation decisions failing to meet global standards of regulatory quality. Indeed, in too many cases, decisions are disproportionate or unduly precautionary or unpredictable, or take too long, or impose unjustified costs. These weaknesses, and their outcomes, are potentially a structural impediment to the effective implementation of the EU’s ambitious policies for a greener and more sustainable future. A programme of reform should be established to improve the governance of the EU Administrative State, starting with the adoption of a comprehensive [Law of Administrative Procedures](#).³

Recommendation 1 – The European Commission should, building on earlier work by the European Parliament, develop and adopt a legislative proposal for a comprehensive Law of Administrative Procedures.

Recommendation 2 – The European Commission should expand and tailor the scope of the Better Regulation requirements, its Guidelines and Toolbox to encompass all forms of implementation mechanisms, including regulation (through comitology), substantive guidance, and standards. Particular attention should be paid to coherence with other policy objectives, dynamic impacts, scientific evidence, administrative appeals, and risk-risk.

² ERF Monograph (2019), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erif_monograph_-_risk_management_and_the_eus_administrative_state.pdf.

³ ERF Highlights Note 05 (2016), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_highlights_5_-_lap_rationale_-_jan.16.pdf.

2.2.2. Framework Conditions and Regulation

The Communication recognises the importance of regulations as a part of the wider framework conditions that shape economic activity. In this case, the allocation of capital and other resources to support the EU's recovery and green goals. This is to be welcomed and should be reflected fully in the Better Regulation Toolbox.

However, the Communication fails to adequately consider the specific role that regulations, and the way in which they are implemented, play in creating *incentives to invest in innovation*. Innovation is the single most important driver for prosperity and sustainability in Europe. Ensuring that regulators have a *rigorous understanding*⁴ of the relationship between framework conditions, government interventions and innovation is therefore key. It is regrettably that the Communication fails to outline how Better Regulation is going to concretely support incentives to invest in innovation and to increase the attractiveness of Europe for R&I investments.

*Research by the ERIF*⁵ suggests that the way in which the EU regulates risk affects social attitudes, a determinant of acceptance of new technologies; access to markets; access to ideas and technologies; and, access to capital. Specific problems include delays and high capitalised costs of development due to *'time-to-market' problems*,⁶ stigmatisation of technologies, and high levels of *Defensive R&D*.⁷

Recommendation 3 – The Commission should affirm more explicitly the central role played by innovation in the transition triggered by the Green Deal. Consequently, it should revise the Better Regulation Guidelines to more thoroughly identify the impacts of regulatory processes and decisions on incentives to invest in innovation along value chains.

Recommendation 4 – The Commission should undertake a series of ex post evaluation and benchmarking exercises to identify time-to-market and Defensive R&D problems and their causes, including an appraisal of the assumptions and models used to design EU legislation and of the related implementation processes and mechanisms. Based on these reviews, specific reforms should be identified.

2.2.3. Evidence and Regulation

The Communication provides an important endorsement of the importance of basing regulatory decisions on evidence in general, and on science in particular. A common evidence register is proposed, along with the publication of background papers and evidence used, and the importance of scientific evidence as “a cornerstone” of Better Regulation is articulated clearly. Science, the Communication explains, provides a means of accurately describing problems and developing a real understanding of causality. As a result it provides the means of establishing a credible and convincing intervention logic and evaluating the impact of interventions. These

⁴ ERF Highlights Note 07 (2016), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_highlights_7_-_risk_regulation_and_innovation_-_mar.16.pdf.

⁵ ERF Communication 12 (2013), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_communication_12.pdf_innovation_principle.pdf.

⁶ ERIF Highlights Note 15 (2021), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erif_highlights_15_-_time_to_market_final.pdf.

⁷ ERF Highlights Note 08 (2016), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_highlights_8_-_defensive_r_d_and_innovation_-_jul.16.pdf.

statements are important and their inclusion in the Communication demonstrates a continued commitment by the Commission to use scientific evidence within its regulatory processes.

Despite this, more needs to be done to ensure that regulatory decisions are systematically informed by the *best available regulatory science* provided by the most eminent and relevant experts. The Communication does not elaborate on the pressing need to establish and enforce criteria for *scientific excellence*⁸ and *impartiality*⁹ in regulatory science. To achieve this, new policies are required to establish world-leading *principles and guidelines for scientific integrity*.¹⁰ Effective application of such standards will require additional institutional reforms.

It is also regrettable that the Communication fails to acknowledge and promote important advances introduced by individual EU agencies and scientific bodies as common good practices. A recent example of such progress is the guidance by EFSA on better crafting Risk Communication (insisting, among other things, on the difference between hazard and risk) and highlighting the contribution of social sciences to inform risk regulation. The governance of the procurement, validation, use and communication of scientific evidence should feature more prominently in the Better Regulation strategy of the EU.

Recommendation 5 – The Commission should develop and adopt minimum standards for scientific integrity, covering study quality, assessment of studies, risk communication and selection of relevant and eminent experts that all directorates and agencies must respect. These could be set out, for instance, in a new decision.

Recommendation 6 – The Commission should, as an integral part of its Better Regulation framework, ensure the enforcement of such standards for scientific integrity, as well as the coordination and active promotion of good practices across all EU institutions and bodies – for instance through the Scientific Advisory Mechanism, the Joint Research Centre, and the EU-ANSA network.

2.2.4. Consultation and Transparency

The Communication recognises the role that stakeholder consultation plays in improving the quality of regulatory proposals and in ensuring the legitimacy of decision-making processes. To support these goals, it sets out a series of important reforms, most notably simpler digital questionnaires and a single call for evidence thereby regrouping inputs from various stakeholders. These proposals are to be welcomed.

Digitalisation, including the utilisation of on-line questionnaires mainly structured around closed questions, continues to be the most important theme of the Communication's strategy for stakeholder consultation. There is, as a result, a tendency to conceive consultation as being a form of perception survey. In contrast, relatively little emphasis is placed on public hearings and other forms of dialectical contribution. The strength of such traditional forms of consultation lies in the opportunity for arguments to be tested publicly through discussion and debate. Action is needed to ensure that these insights inform regulatory decision-making at EU-level.

⁸ ERF Monograph (2016), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_-_scientific_evidence_and_the_management_of_risk_002.pdf.

⁹ ERF Monograph (2020), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erif_monograph_on_coi_and_bias.pdf.

¹⁰ ERIF Communication 20 (2021), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erif_-_com_20_-_scientific_integrity_principles_21.pdf.

It is important, however, when grouping together the inputs from various stakeholders to ensure that **scientific evidence is properly respected**. **Regulators should**¹¹ distinguish clearly between evidence obtained through processes of scientific assessment and inputs provided by stakeholders. They should transparently explain what belongs to either processes and the reasons for retaining or discarding the inputs submitted. Scientific arguments advanced by stakeholders should, in particular, be subject to proper scrutiny by eminent and relevant experts to ensure that they meet accepted standards of scientific integrity. Furthermore, the enhanced transparency and public scrutiny promoted by the common evidence register should not erode relevant confidentiality and property right protection standards.

Recommendation 7 – The Commission should actively promote the organisation of public hearings and other opportunities for interactive debate during the elaboration of regulatory proposals, including implementing measures.

Recommendation 8 – Commission guidelines for consultation with stakeholders should ensure that evidence from scientific assessments is not included in any single grouping of inputs and, that scientific papers or findings put forward by stakeholders are fully evaluated to ensure integrity and, if necessary, included with appropriate expert comments.

2.2.5. Regulatory Decision-making and Governance

Alongside the renewed focus on the importance of basing decisions on evidence, the Communication states that decisions to take regulatory action should demonstrate that benefits justify costs. This is a cornerstone of good regulatory governance and the commitment to following this criterion is of paramount importance.

Within the Communication there is the recognition that, in accordance with the EU Treaty, regulatory decisions should be proportionate. However, the Communication does not spell out the precise meaning of this requirement, and existing Commission guidance does not provide detailed indications as to how proportionality is to be demonstrated and scrutinised. This is a major weakness of the EU's regulatory governance.

The **Proportionality Principle** is one of the core principles of the rule of law and of good regulatory governance, and **four basic tests**¹² of its application during the elaboration and implementation of individual EU proposals include:

- *Measures should only target significant, demonstrable problems* – for measures designed to protect human health or the environment this necessitates the use of risk assessments, and the development of clearly defined “intervention logics”;
- *Measures should demonstrate that the problem is targeted directly and can achieve a measurable impact* – this requires the use of scientific evidence to demonstrate a causal relationship and measurable outcomes for health and environmental measures;

¹¹ ERF Communication 17 (2017), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_-_com_17_-_oecd_stakeholder_engagement_17.pdf.

¹² ERF Highlights Note 12 (2020), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erif_highlights_12_-_proportionality_principle.pdf.

- *Measures should be least burdensome* – this requires rigorous assessment of non-regulatory alternatives; the use of outcome-based and performance-based rules; and assessments of [cost-effectiveness](#);¹³ and
- *Measures should preferably demonstrate that benefits exceed costs or at least that they justify costs* – this requires all costs and benefits to be considered including second-order and ancillary impacts such as risk-risk tradeoffs.

The emergence in several Member States and EU bodies of practices such as [Risk Management Option Analysis \(RMOA\)](#)¹⁴ is highly relevant for the evolution of the EU's Better Regulation Strategy in this respect. Experience with RMOA should inform the design of future legislation at EU-level, including laws designed to realise the ambitions of the Green Deal and their implementing measures.

Recommendation 9 – The Council of the EU Ministers should adopt dedicated Conclusions calling for a more robust and systematic application of the Proportionality Principle.

Recommendation 10 – The Commission should define the meaning and usage of the Proportionality Principle, possibly in the form of a Communication. The Communication should be informed by 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. The document should also recognise the need to transparently appraise alternatives, risk-risk, and socio-economic impacts when developing risk management decisions, basing estimates of the resulting benefits on the weight-of-evidence.

Recommendation 11 – A new Toolkit should be developed by the Commission that provides detailed operational guidance for the application of the Proportionality Principle Communication, including methods of complying with the four core tests of proportionate action

Recommendation 12 – Compliance with the four tests of proportionate action should be one of the prominent formal ‘quality’ requirements applied by the Regulatory Scrutiny Board to all measures, including those that implement complex risk management laws.

2.2.6. Regulatory Uncertainty

Part of the Communication focuses on improvements that need to be made to the Better Regulation Toolbox, so as to implement new regulatory objectives and principles adopted by the Commission. This includes providing guidance for the application of the **“do no significant harm”** requirement, a new principle informing regulatory decision-making. While not explicitly mentioned in the Communication, another idea is being considered by the Commission (for instance in its Chemicals Sustainability Strategy): the concept of **“essential use”** – according to which the availability (and use) of existing technologies and the development of new ones should be restricted solely to applications deemed by regulators to be ‘essential’.

¹³ ERF Highlights Note 11 (2020), at https://www.erforum.eu/uploads/2/5/7/1/25710097/erf_highlights_11_-_cost_effectiveness_analysis.pdf.

¹⁴ ERF Highlights Note 14 (2020), at https://www.erforum.eu/uploads/2/5/7/1/25710097/erf_highlights_14_-_rmoa.pdf.

These new principles are intended to support the delivery of wider sustainability and green goals of the EU. However, clear and operational definitions are lacking, and their systemic application is novel and untested. Their potential unintended consequences are, as yet, little understood or acknowledged. The [challenges](#)¹⁵ of how to implement them without engendering regulatory uncertainty remain outstanding. Creation of systemic regulatory uncertainty could make it more difficult for the EU to achieve its social, economic, and environmental goals.

Unless their application is shaped by robust and well-designed guidance, these new principles could amplify risk aversion, limit the development and dissemination of new technologies, create barriers to the retention of existing investments, increase administrative discretion in implementation decisions, and erode incentives to invest in innovation.

Recommendation 13 – A new toolkit is needed to provide detailed guidance for the application of the “do no significant harm” principle to the development of new legislative measures and to the implementation of existing ones. This guidance should recognise explicitly the potential for this new regulatory principle to create systemic uncertainty and demonstrate how this will be avoided.

Recommendation 14 – The EU institutions should launch a structured and informed society-wide debate on “essentiality” and assessment of the socio-economic benefits of using ‘safety’, ‘risk’, and ‘sustainability’, rather than ‘essentiality’, to regulate the use and development of technologies. This will provide a better understanding of the context within which new, untested ideas are being proposed.

2.2.7. Ex Post Evaluation

The Communication sets out a series of reforms to enhance the impact of ex post evaluations and confirms the importance of the *“evaluate first” principle*. Reforms include greater co-operation with co-legislators to strengthen review and monitoring clauses in legislative proposals; and, a greater focus on unintended consequences and cumulative impact.

[Ex post evaluation](#)¹⁶ is one of the most important regulatory tools. Used well it can help enhance the effectiveness of existing laws, reform implementation processes, and examine assumptions on which laws are based. It can also be used to identify regulatory obstacles that may impede progress towards achieving wider social, economic, and environmental goals. One of the ways it can achieve these goals is by greater focus on ‘horizontal’ lessons from different sectors and regulatory domains. To date, relatively few ex post evaluation exercises have been established to do this. More needs to be done to make greater use of this knowledge to help the EU deliver its ambitious goals.

Recommendation 15 – The Commission should revise the ex post evaluation guidelines to explicitly identify ‘horizontal’ issues that may affect incentives to innovate or may create obstacles to the allocation of capital to the EU. It should include implementation processes undertaken by the EU Administrative State. Possible issues could include ‘time-to-market’, Defensive R&D, access to technologies, as well as underlying regulatory assumptions and modelling.

¹⁵ ERIF Highlights Note 16 (2021), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erif_highlights_16_-_essentiality.pdf.

¹⁶ ERF Communication 13 (2014), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_-_com_13_-_ex_post_guidelines_14.pdf.

Recommendation 16 – The Commission should ensure that the application of new, novel, and untested regulatory principles, most notably ‘essentiality’ and ‘do no significant harm’, should be subject to rigorous ex post evaluation.

2.2.8. Regulatory Oversight

An important element of the new Communication is the continued commitment to a strong role for the Regulatory Scrutiny Board (RSB) in ensuring oversight of the Commission’s regulatory proposals.

The RSB has, over time, contributed to improving the quality of law-making at EU-level and maintaining the credibility of the Better Regulation arrangements. The Board has proven its competence and efficiency also during the extraordinary policy and regulatory situation caused by the COVID-19 pandemic.

The Communication argues that the scope of the RSB’s work should not encompass the political objectives and choices made by the Commission. Whilst it is important to recognise that the choice of overall strategic goals by the Commission must remain within the domain of politics, the *selection of the means* of pursuing such goals should be subject to review and oversight. There should be coherence between the ‘ends’ of policies and the ‘means’ chosen to pursue them. If this is not scrutinised, then there is risk of regulatory failure. Avoiding failures is of particular importance when the EU institutions are pursuing ambitious political goals that will require a series of sector specific regulatory strategies. Fully empowered oversight institutions can also ensure that there is coherence and synergies between the different regulatory strategies, and consistency in the baseline paradigms underpinning the analyses. They furthermore contribute to preserving the neutral and rigorous application of good regulatory practices and instruments vis-à-vis political agendas and time pressures.

Recommendation 17 – The scope of the RSB review should be broadened to also consider the coherence between regulatory strategies and wider political goals, notably with regard to the identification of all relevant options and their prioritisation.

2.2.9. Foresight

Integration of the findings from ‘Foresight’ programmes into the law-making process can help identify potential regulatory issues and, potentially, help make the overall regulatory framework fit for the future. It helps place regulatory decision-making in a wider context of anticipating and, at the same time, stimulating dynamism in society and the economy. Foresight helps highlight the various opportunities and benefits from innovation and not only possible risks. This is recognised by the Communication and is to be welcomed.

It is, however, important to recognise the limitations of the insights that can be drawn from Foresight programmes. Policy interventions that are informed by Foresight ideas should not be elided with concepts of evidence-based decision-making, particularly when dealing with risks posed by technologies or lifestyles to health, safety, and the environment. There should remain a clear distinction between *evidence obtained from scientific assessments and the findings from Foresight* programmes. Scientific assessments are based on the principles and guidelines of scientific integrity. Moreover, scientific arguments included in the findings of Foresight programmes should be assessed to identify the extent to which they meet accepted standards of scientific integrity.

Recommendation 18 – When expanding its Better Regulation guidelines to include Foresight for policy-making, the Commission should ensure that a clear distinction is drawn between different types of evidence, and the quality standards they must meet, particularly when examining proposed risk management measures.

3. ADDITIONAL ISSUES

The new Better Regulation Communication begins to develop important ideas that will contribute to the achievement of the EU's ambitious social, economic and environmental goals. However, research by ERIF suggests that if the EU is to deliver these, particularly the Green Deal goals then the Better Regulation strategy needs to consider a number of additional themes more rigorously and systematically, on top of what outlined in the remarks above. Specifically:

- Innovation (section 3.1.)
- Allocation of capital (3.2.)
- New Technologies (3.3.)
- Human Consequences (3.4.)

3.1. Innovation

Delivering the Green Deal will require significant investment in innovation, particularly by the private sector. This is widely accepted. The private sector is part of the solution to contemporary societal challenges. A challenge facing regulators is to ensure that the regulatory framework maximises incentives and minimises obstacles to invest and operate. It must **favour 'positive' rather than 'negative' decisions**. This issue is not considered explicitly in the new Communication.

Overall, the Green Deal implies that there will be two distinct, and separate, groups of decisions: on the one hand, discontinuing the status quo (i.e. reducing or even abandoning the usage of current technologies and production systems), whilst, at the same time, proactively embracing new technologies, business models, and modes of production. However, the two types of decision are not necessarily related, nor can they be assumed to occur automatically.

As raised in Point 2.2.2. above as well, work by the ERIF has identified a number of [policy, organisational and methodological solutions](#)¹⁷ to address existing regulatory obstacles to innovation. Among the latter are recourse to [hazard-based approaches](#)¹⁸ only, loss of [access to key materials and technologies](#),¹⁹ disproportionate use of [precaution](#),²⁰ market stigmatisation, high levels of [Defensive R&D](#),²¹ extended ['Time-to-market'](#),²² unpredictable risk management,

¹⁷ ERF Monograph (2015), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/monograph_innovation_principle.pdf.

¹⁸ ERF Highlights Note 02 (2015), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_highlights_2_-_hazard-based_regulation_-_nov.15.pdf.

¹⁹ ERIF Highlights Note 16 (2021), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erif_highlights_16_-_essentiality.pdf.

²⁰ ERF Highlights Note 03 (2015), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_highlights_3_-_precaution_-_dec.15.pdf.

²¹ ERF Highlights Note 08 (2016), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erf_highlights_8_-_defensive_r_d_and_innovation_-_jul.16.pdf.

²² ERIF Highlights Note 15 (2021), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erif_highlights_15_-_time_to_market_final.pdf.

and a lack of policy coherence. Better Regulation principles and tools provide a means of assessing Green Deal policies and proposed measures to ensure that these problems are recognised and considered explicitly.

Recommendation 19 – Requirements to apply the Innovation Principle to all proposed policy, legislative and implementing measures should be strengthened, and new guidance drawn up to ensure that it is used to highlight incentives and obstacles to invest in innovation.

3.2. Allocation of Capital

EU policy-makers accept that delivering the Green Deal will depend upon a major allocation of capital by the private sector to investment in the EU, encompassing innovation, new production technologies, and processes, new products and services, and re-equipping existing facilities. For this to happen, there must be a large number of 'positive' decisions by the private sector to allocate capital to a Green Deal Europe rather than in pursuit of opportunities elsewhere. It is, therefore, essential that EU regulators recognise the basis on which capital is allocated by private sector enterprises and the framework conditions that make the EU an attractive location for investors.

Corporate finance principles and practices are standard, well-established globally, and employed by most major companies in Europe as well. They distinguish rigorously between financing decisions (concerning issues such as gearing, solvency, liquidity, and cash servicing costs), and *investment decisions*. It is this latter type of decision that determines whether to allocate capital, based on projects achieving the after-tax risk-adjusted cost of capital. This requirement is set by global capital markets and is not, in general, affected by the way in which companies are funded or by the social priorities of governments. Decisions by bigger investors directly affect also Small and Medium-sized Enterprises, which often operate as part of the wider innovation ecosystem.

Better Regulation tools provide a means of assessing policy and legislative design to ensure that capital allocation decision-making processes are recognised explicitly, such that the EU becomes an attractive, dynamic and predictable location for investment. They can also identify regulatory factors that weaken framework conditions, in areas such as protection of property rights, access to markets, access to technologies and ideas, respect for the rule of law, regulatory certainty, and utilisation of financial resources.

These issues are not considered in the Communication.

Recommendation 20 – The Better Regulation guidelines should be expanded to develop an “Allocation of Capital Test”. This should be applied to policy and legislative proposals, and could form part of the ex post evaluation programme. The ‘test’ should consider two issues: first, the impact of a proposal, or existing implementation process, on the framework conditions for the allocation of capital, including property rights, access to markets (including time-to-market and restrictions on use of technologies), access to technologies and ideas, rule of law, regulatory certainty, and the extent to which financial resources are diverted into defensive R&D; and, second the impact of proposals on the ‘investment decision’.

3.3. New Technologies

It is a foundational assumption of the Green Deal that new, breakthrough technologies will emerge, in response to the EU's policies, thereby facilitating economic and social transformation. Such an assumption is promising but needs to be grounded in evidence and reviewed regularly to ensure that remains credible. Above all, the framework conditions must be created and maintained for it to materialise. The Communication does not present the rationale and evidence supporting such an assumption nor does it acknowledge the related challenges and propose mechanisms to manage them.

Experience across OECD countries suggests that priority should be given to good regulatory principles (most notably technology neutrality) and practices, such as economic incentives rather than command-and-control rules. Regulatory standards should be based on performance and outcome rather than design. Safety rules are better focused on applications rather than technologies. And, in overall terms, the regulatory framework should maximise the opportunity for investors and entrepreneurs to compete. International regulatory cooperation should be pursued on these bases, too. Where necessary incremental change should be supported. The *European economy and industrial base* have an impressive track record and still possess a remarkable potential for incremental innovation. These ideas should be explicitly embedded in the EU Better Regulation framework.

Recommendation 21 – The Commission should develop a formal policy for the regulation of new technologies. This should be based on global best practices. Better Regulation principles and guidelines should be revised to ensure that the requirements of the policy for new technologies are respected when new legislative proposals are developed.

3.4. Human Consequences

One of the most important, and largely overlooked, aspects of Better Regulation policies and practices is that they highlight the human consequences of policy, legal, and regulatory decisions. They remind regulators that government actions have consequences for the lives, livelihoods, aspirations, health, and well-being of citizens. This is one of the greatest strengths of public action. Better Regulation policies and tools help, therefore, to *bolster legitimacy of measures and consent*. Maintenance of consent is a critical requirement if the EU's Green Deal is to achieve its ambitious goals.

For instance, policies designed to promote radical economic and social change will entail disruption: some activities will cease and other will emerge. Often this will occur in areas that suffer from a lack of economic dynamism. Part of the Green Deal recognises this, and foresees supporting funding through the “Just Transition Mechanism”. Besides financing compensatory and mitigating schemes, nonetheless, governments must make informed judgements about the nature and timing of proposed measures, and allocate public funds effectively and efficiently. Better Regulation good practices complement financial support and improve decision-making, particularly by better understanding the social costs emerging from the erosion of human capital and ‘health-health’ impacts (whereby loss of income leads to risky personal behaviours).

Another important aspect of the Green Deal is that it will require a major change in behaviours by most of Europe's citizens, affecting domains as disparate as consumption of energy, employment, and mobility. Yet the relative consequences of such behavioural changes may vary between different social groups. It should not be overlooked that poorer and less mobile citizens

may disproportionately bear such negative impacts. This may erode acceptance of the Green Deal amongst wide parts of society. Understanding, identifying, recognising, and explicitly ameliorating these **distributional impacts** will be critical for the design of measures that avoid regulatory failure and ensure continuance of consent. Better Regulation provides the governance framework for ensuring that these evaluations take place.

These issues are not fully tackled by the Communication, beyond the commitment to “leave no-one behind” in the Green Deal transition.

Recommendation 22 – The Commission should strengthen the requirements and methodological guidance for assessing and understanding the dynamic impacts of proposed legislative and implementing measures set out in the Better Regulation guidelines, particularly with regard to distributional impacts on socio-economic and health conditions across Europe.

4. CONCLUSIONS

Throughout the OECD area, Better Regulation has become an important philosophy of governance. It seeks to strengthen consent to law-making and to the actions of the State needed to implement legal requirements. The EU is a world-leader in the application of Better Regulation principles and tools. As such, it is ideally placed to use this expertise to help [deliver the goals of the Green Deal](#),²³ and other ambitious policy objectives, whilst avoiding negative unintended consequences and sustaining the support of citizens.

As the EU institutions have scaled up the complexity and ambition of their policy objectives to achieve the Green Deal, so they must strengthen their Better Regulation capacity. At the same time, they need to explicitly recognise and address policy and legislative tradeoffs (and maximise synergies). Availability of critical raw materials, as well as chemical and metallic technologies will, for example, play a critical role in achieving mobility and renewable energy goals. Similarly, there will be a need to resolve the tensions between the circularity of economic activity and restrictions of materials in waste streams, or again between protection of nature and ambitions to reshape the range of technologies used in the agro-food sector.

Other important risk-risk tradeoffs are almost endemic in a policy endeavour such as the Green Deal. Whilst ancillary co-benefits may materialise, net risks may be increased rather than reduced as an unintended consequence of regulation. Policies designed to restrict the use of certain mobility technologies may, for example, increase environmental damage when all aspects of usage and production are considered. Similarly, regulatory actions to limit usage of certain chemical or metallic technologies may trigger substitution with less well-understood (and potentially less safe) alternatives or a loss of important benefits during the production process or for consumers. Understanding the dynamics that foster the pacing and diffusion of innovation across the economy, including the development of the necessary infrastructure, is equally important. The transition set out by the Green Deal is inevitably triggering changes and tradeoffs, which should be fully recognised.

Better Regulation tools offer a critical means of identifying these dynamic impacts, and thinking about making and implementing law that helps governments ensure predictability, avoid

²³ ERF Highlights Note 13 (2020), at https://www.eriforum.eu/uploads/2/5/7/1/25710097/erif_highlights_13_-_green_deal_and_br.pdf.

regulatory failure, and sustain legitimacy and consent. It is at its most relevant for good governance when governments set out to deliver complex and radical policies that require extensive legal and regulatory decision-making. Extensive use of the principles and tools of Better Regulation can help the EU deliver the aims of the European Green Deal. Building on the new Commission Communication and existing Better Regulation guidelines, this ERIF Communication identifies a series of additional recommendations that will, if adopted, help the EU deliver on such an important transition.

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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 members.

European Regulation and Innovation Forum

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

In order to achieve this, the Forum applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory governance, decision-making structures, tools, and processes; the risks and benefits of new and emerging technologies, and of lifestyle choices; obstacles and incentives for innovation, including the regulatory framework; and, the importance of high quality scientific evidence for better regulation. This approach is highly relevant at present, as the EU recovers from the COVID-19 pandemic and undertakes an effective and proportionate transition to the new economic and societal models pursued by the European Green Deal.

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

- Necessary, effective, and proportionate (resting on a rigorous definition of the policy objectives, as well as a clear and comprehensive description and assessment of problems and their underlying causes);
- Based on credible evidence, particularly science, that supports the use of the powers of the State;
- Informed by a robust and transparent understanding of costs and benefits, particularly dynamic impacts such as risk-risk tradeoffs;
- 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.

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