



## **EUROPEAN REGULATION AND INNOVATION FORUM – COMMUNICATION 23**

**BETTER REGULATION, PROSPERITY, TRANSITION AND RESILIENCE  
IDEAS FOR THE NEW COMMISSION**

**December 2023**

## EXECUTIVE SUMMARY

Our conviction is that Better Regulation is a key tool for the EU and indeed all governments to deliver prosperity, competitiveness, green transition, strategic resilience and public accountability. The EU has a strong track record in Better Regulation. The EU can and should continue to build on this track record as a key policy tool for delivering economic and social objectives.

This report suggests four priority areas for **Better Regulation focus**:

- **Regulatory Policy** – to strengthen policy coherence and integration, internal consistency, proportionality, scientific integrity, transparency and member state coordination, and to identify and avoid adverse effects from ‘horizontal’ risk management policies.
- **Law-Making Process** – to strengthen impact assessment, consultation and ex-post evaluation, and to avoid delegation of issues to administrative implementation that should be decided in the primary legislative process.
- **Implementation Mechanisms** – to strengthen scientific assessments, transparency, accountability and use of expertise, and to strengthen scrutiny and due process in substantive guidance.
- **Due Process Standards** – to introduce a Law of Administrative Procedure, a basic requirement for the executive function of any governing entity, and to strengthen scientific appeals mechanisms, scientific oversight, regulatory oversight (through the Regulatory Scrutiny Board), and to provide binding standards of good administration for reference by the European Courts.

In offering concrete recommendations for consideration by the incoming European Commission and Parliament, ERIF is very much aware of the broad scope of the Regulatory Agenda and of the need for realistic prioritisation. However, we believe it is possible to identify and deliver on a number of **tangible actions** that would continue to strengthen the Better Regulation approach. These are set out in this Communication as follows:

- **Overall Governance** – including review of the Inter Institutional Agreement on Better Law Making, adoption of a comprehensive Law of Administrative Procedure, a strengthened mandate for the Regulatory Scrutiny Board, a Communication on the Proportionality Principle, and a revised Communication on Better Regulation.
- **Evidence-Based Decision-Making** – including adoption of common principles for Scientific Integrity in Regulatory Decision Making, establishment of a Non-Food Consumer Safety Agency, establishment of an Office of Scientific Standards and of an Independent Appeals Board for Scientific Assessments, a new network of Independent Scientific Committees, and adoption of Principles for Access to Expertise and Impartiality in the Functioning of Scientific Committees.

With these measures, we are confident that Better Regulation can play a key role in reducing regulatory risk, strengthening the investment environment and the business case for capital investment in the EU, and enhancing desired social and environmental outcomes.

# 1. INTRODUCTION

**This ERIF Communication is a contribution to the incoming European Commission. Building on ERIF's extensive research,<sup>1</sup> it sets out the main areas for the further improvement of the EU's Better Regulation agenda. Used well and exploited fully, this will play a critical role in creating the conditions for the European Union to achieve its primary socio-economic goals.**

**Over the last decade, the EU institutions have built political commitment in support of achieving ambitious, overarching and systemic goals, such as greater prosperity, transition to a greener economic model and stronger strategic resilience.** This important commitment should be recognised and respected.

**Delivering these goals will, however, be difficult.** The EU faces strong headwinds from a range of internal and external factors including the impact of the war in Ukraine, higher energy costs, geo-political uncertainty, recovery from COVID-19, falling living standards, stagnant economic growth, de-industrialisation and de-globalisation, as supply chains restructure.

**Whilst there is widespread support for the overall 'ends' being pursued by the European Union, there are concerns about the 'means'.** In some cases, there is a clear divergence of opinion about the effectiveness of proposed solutions. In other cases, there are concerns about the lack of coherence between different policies or pieces of legislation. There are also emerging concerns about the potential unintended consequences of radical and untested new approaches for the management of risk and hence the development of technologies.

To help navigate through these obstacles and to deliver its ambitious goals, the EU possesses a wide range of policy levers, including financial, research, industrial, trade, agricultural and energy. **One of its most important policy levers, however, is regulatory policy, and specifically those regulations that influence allocation of capital, incentives to innovate, economic dynamism and technology development.** Regulations create obligations and hence shape incentives and obstacles that, in turn, influence behaviour of citizens, firms and investors.

In the light of this, ERIF's research has considered critical success factors for the design and implementation of the existing Better Regulation agenda. Whilst the EU has already embraced many of these factors, **more needs to be done to identify and resolve persisting cross-cutting governance weaknesses that limit the effectiveness of the Better Regulation agenda and hence of specific regulations and of regulatory policy.**

**This Communication draws attention to current governance challenges, and sets out constructive ideas for using good regulatory principles and tools fully and systematically to overcome them.** Work by ERIF has focused on the impact of regulations on four critical, underlying 'drivers' that influence the ability of the EU to achieve its socio-economic goals effectively and proportionately. Specifically: **(1)** Economic Competitiveness; **(2)** Allocation of Capital; **(3)** Scientific Integrity (of policy, legislation and implementation mechanisms); and **(4)** Incentives to Innovate. Ensuring that regulations do not create obstacles to the full exploitation of these 'drivers' will be essential for the delivery of the EU's goals. This can be achieved through a programme of reforms targeting existing challenges, using the findings from ERIF's research and by improved application by the EU of the Better Regulation agenda. A series of ERIF Highlights Notes complement information on how Better Regulation can support these four drivers.<sup>2</sup>

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<sup>1</sup> For information on the European Regulation and Innovation Forum (ERIF), see the last page of this Communication, and visit [www.eriforum.eu](http://www.eriforum.eu).

<sup>2</sup> See *ERIF Highlights Note 23 Scientific Integrity, Novel Regulatory Philosophies and Better Regulation, 2023*; *ERIF Highlights Note 24 Allocation of Capital, Novel Regulatory Philosophies and Better Regulation, 2023*; *ERIF Highlights Note 25 Innovation, Novel Regulatory Philosophies and Better Regulation, 2023*; and *ERIF Highlights Note 26, Competitiveness, Novel Regulatory Philosophies and Better Regulation, 2023*. Underlying research on Novel Regulatory Philosophies can be accessed at [www.eriforum.eu/NRPs](http://www.eriforum.eu/NRPs).

## 2. BETTER REGULATION

### 2.1. Purpose

**Better Regulation is a philosophy of government. It seeks to strengthen consent to law making and to those actions of the State that implement legal requirements. It aims to ensure that agreed societal objectives are pursued effectively and proportionately, and that actions are legitimated.**

Application of Better Regulation to decision-making strengthens consent in two ways: first, the process of making decisions is made more predictable, participatory, transparent and accountable; and second, the outcomes of decisions are more effective, proportionate and enforceable.

Better Regulation focuses on the type and quality of regulation, including implementing decisions. It recognises that regulation can trigger benefits to individuals, societies and the environment, and that it plays an important role in determining the allocation of capital, incentives to innovate and economic dynamism, and hence prosperity. It highlights the need to understand tradeoffs when regulating, and to ensure that actions of governments are coherent. It also accepts that regulation seeks to change behaviours and that, in many instances, this will trigger dynamic responses, including positive and negative unintended consequences.

Better Regulation programmes typically encompass political commitment and legal requirements, organisational arrangements, regulatory policy decisions and methodological guidance. Programmes include tools such as stakeholder consultation, impact assessment, common standards for scientific integrity and ex post evaluation, supported by institutionalised oversight, political commitments and laws of administrative procedure. Taken together, these arrangements and tools seek to ensure that laws, and the actions taken to implement them, are:

- Necessary, effective and proportionate;
- Based on credible evidence, including scientific assessment, that supports the use of the powers of the State;
- Informed by a transparent understanding of costs and benefits, including dynamic impacts, such as risk-risk;
- Demonstrate that benefits justify costs;
- Developed using transparent decision-making processes; and
- Reviewable over time and subject to appeals and redress mechanisms

### 2.2. Importance

**Better Regulation provides decision-makers with a way of thinking about making and implementing laws that can help ensure predictability, avoid regulatory failure and sustain legitimacy. Indeed, it is at its most relevant for good governance when governments set out to deliver ambitious economy and society-wide goals. In such situations, it is vitally important to understand thoroughly distributional impacts and the complex relationships between regulation, innovation and the allocation of capital.**

This is of particular importance for the European Union as it seeks to deliver its ambitious socio-economic goals. The European Commission has acknowledged the importance of Better Regulation for helping deliver the transition to a greener economy. It recognises that Better Regulation provides a governance mechanism that can ensure better integration of policies, more efficient policy choices and the design of measures that are least burdensome. It can also help to integrate institutional actors.

## 2.3. European Commission and Better Regulation

Over more than two decades, all of the EU institutions have implemented a series of substantial reforms. Indeed, research by the OECD, examining the comparative performance of members, shows that **the EU has become a world-leader in the application of Better Regulation principles, policies and tools**. Stakeholders recognise this and it is to be celebrated.

Better Regulation has become an integral part of the decision-making of the European Commission. It has, moreover, improved steadily over time. Notable highlights include:

- **Political Commitment** – this is set out in the comprehensive Inter-institutional Agreement on Better Law-making between the European Parliament, the Council and the Commission. Moreover, recent Commissions have included a senior position, often a Vice-President, with a dedicated Better Regulation portfolio. Since 2010, the Commission has also accepted the “evaluate first” principle when assessing the need for and design of legislative interventions.
- **Organisational Arrangements** – amongst the major organisational improvements<sup>3</sup> are:
  - Expansion of the mandate and capacity of the Secretariat-General for Better Regulation issues, supported by Better Regulation units in many DGs;
  - Establishment of agencies and independent scientific committees to undertake and develop risk and safety assessment opinions in specific sectoral (vertical) regulatory domains;
  - Institutionalisation of a central oversight body (the Regulatory Scrutiny Board – RSB) with responsibility for reviewing draft impact assessments and evaluations;
  - Strengthening of the JRC as a provider of research and analyses supporting decision-making;
  - Creation of a Scientific Advisory Mechanism nurturing the interface with the European scientific, engineering and technical academies; and
  - Setting up of the Fit-For-Future Platform for the review and simplification of the *acquis communautaire*.
- **Policies and Guidance** – the Commission has issued a series of policy documents that define the rationale for Better Regulation and the application of good regulatory principles. These include the application of the Precautionary Principle, the Innovation Principle and the integration of foresight into Better Regulation. Some steps have also been taken to define standards of scientific integrity, such as rules of procedure of the DG SANTE scientific committees.

To implement its Better Regulation policy, the Commission has adopted comprehensive and detailed guidance, comprising toolkits with procedural and methodological instructions for high quality analysis and effective public consultation. A web-portal allows user-friendly interaction between citizens and the Commission, as well as facilitating access to documents relevant to the decision-making process.

Nevertheless, the growing recognition of the extent of competitiveness challenges and the massive scale of the transition to a greener and more resilient and innovative economy, suggests that the EU should continue to build on its Better Regulation track record to support delivery of its desired economic, social and environmental outcomes.

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<sup>3</sup> The other EU institutions have also established important organisational arrangements. The European Parliament has, for instance, set up a well-functioning, in-house Research Service to support MEPs and to provide relevant analyses to citizens. At the level of the European Council, the Working Party on Better Regulation is an influential part of the Competitiveness Council. Institutional strengthening of this nature is vital for the continuous and sustained development of the Better Regulation agenda at EU-level.

## 3. CROSS-CUTTING GOVERNANCE

### 3.1. Importance

**A focus on governance issues is essential for improving the quality of law-making and its implementation. It helps identify good practices from which to draw lessons and to understand why recurring challenges persist. It also provides insights as to how on-going practices might be improved, enhancing the effectiveness of future decision-making.**

Better governance of law-making, implementation and policy, will also help bring together the legislative instruments that are needed to facilitate the achievement of the EU's ambitious socio-economic goals, strengthening coherence and delivering effectiveness and proportionality.

ERIF research suggests that the EU's regulatory governance would benefit from improvements in four domains of the decision-making context:

- Regulatory Policy (section 3.2.)
- Law-Making Process (3.3.)
- Implementation Mechanisms (3.4.)
- Due Process Standards (3.5.)

### 3.2. Regulatory Policy

**Policy interventions, including regulations, frequently seek to change behaviours and increasingly promote economic and social change. In recent years, the EU has adopted a 'neo-dirigisme' approach that uses regulation as an intended driver of change through prescription, direction, command and control, rather than an enabler of innovation or allocation of capital.** Regulation is used to favour "strategic technologies" as opposed to supporting technological neutrality, for instance. There is, however, little evidence that this approach has, as yet, delivered positive economic or social change.

Whilst the Commission has recognised the importance of the regulatory framework for stimulating innovation and fostering competitiveness, it has also acknowledged some of the current challenges hampering its smooth and effective functioning. To address these challenges, the Commission has placed a major emphasis on regulatory experimentation, notably through the use of so-called "regulatory sandboxes" (Box 1).

#### Box 1

##### Regulatory Sandboxes – Observations

This new approach offers a number of advantages, most notably flexibility and adaptability. It also facilitates communication between regulators and regulated parties. There are, however, risks from seeking regulatory agility primarily through experimentation:

- Unless well-designed and managed, 'sandboxes are at risk of regulatory capture or uncompetitive behaviours;
- Sandboxes were originally designed for very limited circumstances, most notably advanced capital markets and FinTech. Applications elsewhere may not be necessarily appropriate or effective;
- Experimentation may not create the predictability needed to justify major R&D investments;
- Use of sandboxes tends not to be technologically neutral; and
- Its outcomes are a series of derogations, a weak form of property right that depends on administrative discretion. Without strong property rights, it is difficult to justify allocation of capital.

Arguably, a better approach would be to focus on outcomes-based regulation and technological neutrality.

Although there are merits in seeking to develop new forms of regulation to encourage innovation, the EU's regulatory policy faces a number of greater challenges that undermine governance. These should be addressed as a matter of urgency. Specifically:

- **Coherence and integration** – the Better Regulation process could be better exploited to ensure policy coherence and integration. For example, the strategies designed to promote industrial policy, research and innovation are not aligned with the new approach to risk and technology management being adopted by the Commission (Novel Regulatory Philosophies), and may be jeopardised by it.
- **Internal consistency** – Better Regulation tools could be deployed more effectively to ensure greater internal consistency between policy strategies and specific legislative initiatives. They could help clarify priorities and identify synergies, as well as highlighting trade-offs between conflicting objectives. Too many initiatives fail to acknowledge that “you cannot have it all” and that trade-offs are a necessary and unavoidable part of legislative and administrative decision making.
- **Proportionality** – EU decision-making rests on proportionality. It is a fundamental principle of EU law. Whilst this is recognised and restated in a series of policy documents by the EU institutions, the Better Regulation process has not yet set out clear and uniform guidance on how to apply the principle of proportionality. This is a major weakness of the current EU policy-making, legislative and implementation process.
- **Horizontal Risk Management** – there is an increased tendency for the Commission to expand the remit and scope of application of ‘horizontal’ risk management frameworks, encompassing legislation and implementation mechanisms, to the detriment of well-established and well-functioning vertical frameworks. This is a specific characteristic of the Commission’s new approach to risk and technology management. It replaces the specific focus on technologies, products and applications developed and refined over time, with aggregation (‘grouping’), lack of proportionality and potentially non-specific assessments of risk. It limits recourse to relevant scientific excellence and expertise. Over time, it may lead to reduced protection for man and nature, increased net risk and the loss of safe use of substances.
- **Scientific Integrity** – the use of scientific evidence in rule-making is not yet based on codified principles, uniform requirements and state-of-the-art guidelines for scientific integrity, for example on Weight of Evidence procedures and research protocols. There is also a lack of recognition of the nature of bias, and of the conflicts of interest that may cause it. A disproportionate focus on financial conflicts of interest has reduced access to many of the most eminent and relevant scientific experts. This weakens the quality of scientific assessments, potentially leading to lower levels of health and environmental protection and putting at risk wider socio-economic goals of the EU.
- **Transparency** – there is a preference for “output transparency” rather than “procedural transparency” in decision-making processes. The former focuses on access to documents and reduced data confidentiality, whilst the latter considers the validation of evidence, peer review and redress mechanisms. More emphasis is needed to improve confidence in decision-making procedures. At the same time, there is a careful balance to be struck between full public disclosure of confidential data or information and the erosion of property rights. Lack of extensive protection for intellectual property creates strategic risk, limiting incentives to allocate capital or to invest in innovation.
- **Member State Co-ordination** – there is a lack of co-ordination of Better Regulation between the Commission and the Member States. For instance, Member States do not participate systematically in the development of the impact assessments at EU-level and rarely prepare



for the implementation of EU law through national consultations and transposition studies. This leads to possible failings in regulatory design, including a lack of consideration of mechanisms to facilitate early detection of challenges to implement and enforce EU law at the national level. Moreover, the capacity within national governments for evidence-based decision-making varies considerably.

### 3.3. Law-Making Process

It is widely acknowledged that the European Union has developed one of the most comprehensive Better Regulation processes in the OECD area. This has helped, over time, to improve the quality, primarily, of legislative initiatives.

**However, research by ERIF and reports issued by the Regulatory Scrutiny Board, have highlighted a number of areas where the law-making process can be improved.** These include:

- **Impact Assessments** – there is need to make greater use of the impact assessment process to more rigorously investigate the causal relationships between the problem at hand, the agreed objectives and the expected impacts of a proposed intervention (so-called ‘intervention logic’). Furthermore, IAs could investigate more systematically the implementability and enforceability of the proposed measures.

There is also scope to improve the characterisation and quantification of indirect impacts, including adjustment costs and the distributional effects. Too many measures have been developed without recognising that significant disruptions to established economic activity, as a result of regulation, do not lead to a new equilibrium in any reasonable time period. Instead there can be long-lasting damage to human capital and health-health outcomes. These impacts often fall on lagging or deprived areas.<sup>4</sup>

Insufficient attention is paid to unintended consequences, including the dynamic response by affected parties to regulatory requirements, defensive R&D, time-to-market and risk-risk outcomes. Health and environmental interventions often fail to demonstrate that net risk has been reduced.

It is often not clear that benefits justify costs, or that benefits have been assessed rigorously. There is no systemic, full and transparent disclosure of the uncertainties, assumptions and causal evidence related to claimed benefits.

Insufficient use is made of analyses that highlight the cost effectiveness of interventions, particularly when acting to improve protection of man or nature. Cost Effectiveness Analysis requires regulators to identify and quantify the ultimate outcomes of measures, such as improvements in mortality or morbidity.

Draft impact assessments are not made public, limiting opportunities for meaningful consultation during the process of preparing measures. There is also a lack of rigorous justification for not carrying out impact assessments, notably in the context of elaborating implementing and delegated acts.

- **Consultation** – too many public consultations are crafted as perception surveys using closed questions rather than seeking more extensive contributions. Whilst on-line consultations allow for a wide range of stakeholder inputs, they tend to reinforce the tendency to use closed questions as well as inhibiting public debate. Indeed, public hearings, with balanced participation of all relevant stakeholders, are seldom organised. There is also inconsistency in the rigour with which regulators provide feedback, explaining how contributions by

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<sup>4</sup> Part of the EU Green Deal recognizes this and proposes to provide financial support through the ‘Just Transition Mechanism’. However, for this support to be effective, ex ante analysis of policy interventions must rigorously identify potential adjustment effects and take into account their complex nature, including the likely duration of impacts.



stakeholders have been taken into account and, where this has not occurred, the reasons for excluding it.

- **Opacity and Uncertainty** – there is an increasing emphasis on leaving the definition of substantial elements of interventions to the implementation phase of the policy cycle, making extensive use of delegated acts rather than full legislative procedures. This creates systemic uncertainty, increases the discretion enjoyed by officials and limits public scrutiny. Alongside this, the EU institutions make increasing use of trilogues with opaque applications of regulatory management tools.
- **Ex Post Evaluation** – there is insufficient cross-policy or cross-sectoral consideration during the ex post evaluation process, meaning that evaluations rarely investigate “horizontal lessons”. For example, there has been no adequate ex post evaluation of the positive and negative impacts of the regulatory framework on the Framework Conditions for innovation. Important impacts include time-to-market, capitalised costs, diversion of resources, defensive R&D, stigmatisation, adjustment costs and risk-risk outcomes. Better use could also be made of standard values, assumptions and methods.

### 3.4. Implementation Mechanisms

**The scale and nature of the EU’s Administrative State remains greatly underestimated, and its impact on achieving prosperity, transition and resilience is not well understood.** Using science, regulation and guidance, the European Union directly implements complex legislation across a wide range of policy domains, including laws that regulate risk and hence the development and use of technology. Research by ERIF has identified a number of major failings of the EU’s Administrative State. These include:

- **Scientific Assessments** – whilst many scientific assessments remain of high quality, such as those carried out by EMA or the independent SCCS, too many fail to meet globally accepted standards. One cause of this is the “cherry picking” of regulatory science, often combined with unjustified worse case scenarios or safety factors, reliance on low quality or discredited studies, combined with the inappropriate use of the precautionary principle in the process of scientific assessment.
- **Transparency and accountability** – there are problems with the lack of transparency of stakeholder participation and the substantiation of implementing regulatory decisions. Unclear requirements and partial due process standards permit limited public engagement and a lack of exhaustive explanation of the factual basis for the scope and content of decisions. Moreover, no ‘public docket’<sup>5</sup> requirement exists at EU-level. This allows decision-makers to rely upon information that may not be publicly available and hence cannot be scrutinised or challenged.
- **Expertise** – in too many cases, expert groups undertaking scientific assessments lack relevant and eminent expertise. This is a consequence of failing to ensure that eminence and relevance are the primary criteria for the selection of scientific experts. There are number of dimensions to this problem. First, there is increasing use by the European Commission of ‘generic’ scientific committees (associated with ‘horizontal’ risk regulation, for example) where the scientific need is for highly specialised expertise. Second, the Technical Working Group model, a significant implementation mechanism, does not reflect the major differences in scientific and technical expertise that may exist between Member States. Finally, conflict of interest policies place undue emphasis on financial conflicts. This approach overlooks

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<sup>5</sup> One of the key principles of good administration is that all evidence relied on by regulators should be included in the public record. ‘Public Dockets’ are repositories where all such information is collected and made available for public review.

predetermination and other non-financial factors, yet excludes many of the most eminent and expert scientists due to their links with business.

- **Substantive Guidance** – one of the most important implementing mechanisms used by the European Commission is substantive guidance.<sup>6</sup> As with other forms of ‘soft law’, it has the advantage of being able to adapt quickly to the latest methodological advances. However, substantive guidance requires adequate scrutiny and due process to avoid adding disproportionate regulatory and administrative requirements. At present, substantive guidance is not systematically subject to the EU’s good regulatory practices.

### 3.5. Due Process Standards

**One of the defining features of high quality governance is the presence of organisational, legislative and judicial mechanisms to ensure that the actions of the Executive respect the rule of law and comply with the principles of good administration.** This ensures that those affected by the actions of government have confidence in their legitimacy and recourse to appropriate redress mechanisms whenever this is appropriate.

The EU has significant constitutional and institutional restraints on the exercise of the powers of the Executive (‘checks and balances’). However, there are number of ways in which the enforcement of due process standards could be improved. These include:

- **Law of Administrative Procedures** – most national polities in the OECD area have laws that require the exercise of the powers of the executive function to meet widely accepted standards of good administration, and provide affected parties with legally enforceable standards and procedural rights that encompass all significant rule-making and adjudication decisions. The four principles of good administration are transparency and consistency, public participation, public record and accountability. Despite a series of initiatives by the European Parliament over more than a decade, the EU has not yet put in place a law of administrative procedures. In view of the ever-growing impact of regulation and the public administration on all citizens and sectors of society, this is a crucial and indeed perplexing weakness.
- **Scientific Appeals Mechanisms** – scientific assessments, undertaken by the European Commission’s agencies, technical working groups and scientific committees, underpin the implementation of risk management laws. As yet, there is no mechanism at EU-level whereby significant scientific assessments can be appealed and reviewed independently against evident failure to respect agreed procedural requirements or manifest errors by other scientific assessment bodies.
- **Scientific Oversight** – there are two major gaps. First, there are no binding principles and guidelines for scientific integrity. Second, there is no institutional body responsible for drawing up such standards and for enforcing their application. These gaps make it difficult to build trust in scientific assessments and contribute to poor decision-making.
- **Regulatory Oversight** – the Regulatory Scrutiny Board (RSB) is one of the most important institutional characteristics of the Better Regulation agenda. It plays a pivotal role in helping to ensure that proposed interventions meet the standards set out in the Commission’s Better Regulation guidelines. It has also begun to scrutinise implementing regulations. However, it lacks the capacities and powers to fully scrutinise all significant implementing measures

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<sup>6</sup> Substantive Guidance is used to set out detailed technical, scientific or regulatory requirements that must be met to fulfill obligations laid down in EU law and to provide detailed interpretations of statutory obligations, thereby defining requirements or impacts for affected entities. It is drawn up by the Commission, EU agencies and bodies using administrative procedures, and crucially does not fall within the scope of the Better Regulation agenda.

introduced by the EU's Administrative State. The number and importance of such measures will increase dramatically, as the European Union begins to implement its new legislative agenda.

- **EU Courts** – there are significant constraints on the ability of EU courts to meaningfully review decisions, because of a lack binding uniform standards of good administration, including principles and guidelines for scientific integrity.

## 4. RECOMMENDATIONS

Governance reforms are proposed to improve the quality of decision-making throughout the policy cycle, enhancing effectiveness, improving coherence and reducing the risk of regulatory failure. This will underpin the contribution of regulatory policy to the delivery of the EU's socio-economic goals. The reforms focus on **two themes: (1)** Improvements to **overall governance**, including its application to the EU's Administrative State, strengthening regulatory oversight and encouraging greater awareness of the dynamic and unintended consequences of regulation; and **(2)** Enhancing the **role of evidence**, including scientific assessments, in decision-making.

### 4.1. Overall Governance

#### 4.1.1. EU Institutions – Political Commitments

**Recommendation 1:** The EU institutions should formally commit to **a review of the respective application of the provisions set out in the Inter-Institutional Agreement on Better Law-Making**, with a view to identifying the priority areas for reform in each decision-making process within the policy cycle and ensuring that the use of good regulatory principles and practices becomes a binding requirement for each process. The review should inform, in particular, the development of a Law of Administrative Procedures (see Recommendation 2) and ways to apply the Proportionality Principle more robustly and systematically (see Recommendation 4).

#### 4.1.2. EU Institutions – Law of Administrative Procedures

**Recommendation 2:** The EU Legislature should, building on the work of the European Parliament, develop and adopt a comprehensive **Law of Administrative Procedures**, building on the work of the European Parliament.<sup>7</sup> This should embed the principles of good administration into law,<sup>8</sup> 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.<sup>9</sup> It will strengthen accountability and transparency.

#### 4.1.3. European Commission – Mandate of the RSB

**Recommendation 3:** The European Commission should **revise the mandate of the Regulatory Scrutiny Board** so as to strengthen its independence, its expert capacity to review risk management interventions and its powers to reject poor quality proposed interventions.<sup>10</sup>

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<sup>7</sup> 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, adjudication and enforcement decision 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.

<sup>8</sup> Four key principles of good administration: transparency and consistency; public participation; public record; and accountability.

<sup>9</sup> See ERF Policy Note 21, [An EU-Level Law of Administrative Procedures – The Rationale](#), 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.

<sup>10</sup> **RSB Mandate** – the expansion of the RSB mandate should include the following specific actions:

#### 4.1.4. European Commission – Proportionality Principle

**Recommendation 4:** On the basis of an explicit mandate set out in dedicated Council Conclusions, 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. The Communication should include four basic tests:<sup>11</sup> (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.

#### 4.1.5. European Commission – Revised Better Regulation Communication

**Recommendation 5:** The European Commission should revise its **Communication on Better Regulation** to provide for improved scrutiny of the entire policy cycle and to strengthen the focus of regulators on complex dynamic impacts of interventions.<sup>12</sup> 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.

#### 4.1.6. European Parliament – Better Regulation Panel

**Recommendation 6:** The European Parliament should establish an cross-committee, inter-group formation, for instance in the form of a **“Panel”, dedicated to Better Regulation**. The tasks of the Panel should be to provide political steering and backing to specific Better Regulation initiatives within Parliament; exercise inter-institutional scrutiny and accountability for Better Regulation; and promote regulatory reform at the EU level.

## 4.2. Evidence-Based Decision-Making

### 4.2.1. EU Institutions – Political Commitments

**Recommendation 7:** 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**.

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- 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.

<sup>11</sup> See ERF Highlights Note 12, [Proportionality Principle and the Management of Risk](#), 2020.

<sup>12</sup> **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.

#### 4.2.2. EU Institutions – Non-Food Consumer Safety Agency

**Recommendation 8:** 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).<sup>13</sup>

#### 4.2.3. European Commission – Office of Scientific Standards

**Recommendation 9:** 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 10) and to draw up and enforce the new horizontal policy for Principles and Guidance for Scientific Integrity in Regulatory Decision-making (see Recommendation 12).

#### 4.2.4. European Commission – Independent Appeals Board for Scientific Assessments

**Recommendation 10:** 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 9), 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.

#### 4.2.5. European Commission – Network of Independent Scientific Committees

**Recommendation 11:** 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.

#### 4.2.6. European Commission – Principles and Guidelines for Scientific Integrity in Regulatory Decision-Making

**Recommendation 12:** 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-

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<sup>13</sup> See ERIF Monograph, *Scientific Excellence in Consumer Safety – Insights for the Better Regulation Agenda*, 2022; ERIF Policy Note 34, *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.

Making will oversee their development, implementation and enforcement (see Recommendation 9). They will cover minimum standards for study quality, assessment, communication to risk managers of opinions and selection of eminent and relevant experts.<sup>14</sup>

#### 4.2.7. European Commission – Access to Expertise, Impartiality and Functioning of Scientific Committees

**Recommendation 13:** The European Commission should set out, in a new Decision, the **key principles for the selection of scientific experts and for the operation of scientific committees**. It should seek to deliver the twin goals of excellence and impartiality in scientific assessments by combining revised selection procedures for individual experts, with new processes and procedures for the functioning of scientific committees and management of conflicts of interest. These should be minimum standards and should apply to all agencies and directorates, and all forms of scientific committee including Technical Working Groups.<sup>15</sup>

### European Regulation and Innovation Forum December 2023

**Richard Meads and Lorenzo Allio, the Rapporteur and a Senior Policy Analyst at the European Regulation and Innovation Forum, wrote this Communication. However, the views and opinions expressed in this Communication do not necessarily reflect or state those of the European Regulation and Innovation Forum or its members.**

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<sup>14</sup> 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.

<sup>15</sup> Within its provisions, the Decision should:

- Require scientific assessments to be carried out by scientific experts who meet agreed standards of eminence, excellence, and relevance;
- Allow all relevant scientists who meet agreed criteria of eminence, excellence, and relevance to be eligible for selection.
- Establish transparent selection processes to identify all forms of material conflicts of interest that may create bias and are likely to be relevant to the specific work of the group. This should include, but should not be limited to: beliefs, ideals, ideologies, political affiliations, support from or links to interest groups; financial interests; and, personal factors.
- Develop procedures to manage conflicts of interest, such that the most appropriately qualified experts are only excluded in very limited circumstances, such as a credible risk of direct current financial benefits or substantial evidence of personal beliefs or commitments or ideological perspectives that suggest predetermination;
- Require membership of scientific committees to be constituted so as to ensure that decision-makers have access to a range of relevant different types of scientific experts from different scientific disciplines; and,
- Require all outcomes of scientific assessments to be subject to independent peer review. All draft assessments should be reviewed procedurally whilst significant assessment should be subject to an additional substantive review.



## 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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