EUROPEAN REGULATION AND INNOVATION FORUM – COMMUNICATION 22

OECD - PUBLIC CONSULTATION ON THE DRAFT OECD RECOMMENDATION FOR AGILE REGULATORY GOVERNANCE TO HARNESS INNOVATION

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1. EUROPEAN REGULATION AND INNOVATION FORUM

The European Regulation and Innovation Forum (ERIF) is a not-for-profit think tank with the aim of promoting high quality decision-making through Better Regulation. The scope of ERIF's work is primarily addressed to the European Union's institutions. The ERIF was known as the European Risk Forum until January 2021.

The Forum considers 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.

Better Regulation is one of the pre-conditions for governments to deliver major societal goals such as recovering from the COVID-19 pandemic; reaping the potential of the Fourth Industrial Revolution; and transitioning to a greener and more sustainable society. Better Regulation strengthens effectiveness, proportionality as well as consent to law-making and to the actions of the State needed to implement legal requirements. To that end, laws and regulations should be:

- Necessary, effective, and proportionate (resting on a rigorous definition of the policy objectives, as well as a clear and comprehensive description and assessment of problems and their underlying causes);

- Based on credible evidence, particularly science, that supports the use of the powers of the State;

- Informed by a robust and transparent understanding of costs and benefits, particularly dynamic impacts such as risk-risk trade-offs;

- Demonstrate that benefits justify costs;

- Developed using transparent and participatory decision-making processes; and,

- Reviewable over time and subject to appeals and redress mechanisms

High quality decision-making, notably risk regulation, should take place within a structured framework that emphasises a rigorous and comprehensive understanding of the need for public policy action (risk assessment), and a transparent assessment of the workability, effectiveness, costs, benefits, and legitimacy of different policy options (risk management).

Achieving these goals is likely to require extensive use of evidence (especially science); rigorous definition of policy objectives; clear and comprehensive description and assessment of problems and their underlying causes; realistic understanding of the costs and benefits of policy options; and extensive consultation.

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

The ERIF is supported principally by the private sector. The ERIF does not seek to promote any specific set of values, ideologies, or interests. Instead, it considers high quality risk assessment and risk management decisions as being in the public interest. An advisory group of leading academics supports the ERIF's work.

The Forum works with all EU institutions to promote ideas and debate. Original research is produced and is made widely available. As an expert group, the Forum brings together multiple sources of evidence (such as the experience of practitioners and policy-makers; non-EU good practices; and academic research) to assess issues and to identify new ideas. The ERIF directly engages in EU regulatory reform debates through targeted lunches and roundtables. The Forum also regularly contributes to public consultations launched by the EU institutions. A key feature of the ERIF's approach is its emphasis on expert-to-expert dialogue to share views and learn from good practice.

For nearly thirty years, the ERIF, its predecessors, and its founders have supported the adoption by the EU institutions of modern regulatory process management tools, including consultation, impact assessment, ex post evaluation of regulations, and standards for the collection and use of evidence. On the basis of this extensive experience, and its recent work, the ERIF provides comments on the recommendations set out by the OECD in its 'Draft OECD Recommendation on Agile Regulatory Governance to Harness Innovation'.

2. OVERALL COMMENTS

The Draft Recommendation builds on a series of OECD instruments adopted since 1995, including the OECD Recommendation on Regulatory Policy and Governance issued in 2012. These have played a major role in stimulating the adoption by the OECD governments of a number of important regulatory management tools and the creation of new institutions (most notably Regulatory Oversight Bodies) to promote and coordinate their implementation.

The proposed Recommendation comes at an important moment. Early domestic approaches by OECD governments have been introduced and tested, and need now to stand the test of agility, effectiveness, and credibility. With particular focus on the EU context, work by the ERIF has highlighted the following considerations:

- Several governments have begun to recognise the role that regulations, and the institutions and processes that implement them, play in strengthening incentives to invest in innovation, whilst at the same time ensuring a high standard of protection for man and nature. At EU-level, for instance, formal conclusions of the Council of EU Ministers require the adoption and implementation of the Innovation Principle, and the European Commission's Better Regulation toolkit incorporates guidance to enable regulators to assess some of the potential impacts of regulatory proposals on innovation.
- The understanding among regulators of the role that the regulatory framework plays in shaping the incentives to invest in innovation nonetheless remains rather superficial, and related expertise is unevenly present. This calls on governments to consider (i) regulation as one of the enabling framework conditions for innovation;[1] (ii) criteria for 'excellence' and 'impartiality' in regulatory science;[2] (iii) the likelihood of harm, rather than hazard, as the

[1] See ERIF Highlights Note 17 on Risk Regulation and Innovation.

[2] See ERIF Monographs on Scientific evidence and Conflicts of Interest and Bias, respectively.

basis for decision-making;[3] (iv) the increasing relevance of administrative and secondary regulatory decisions for innovation.[4]

- More recently, ERIF's research has identified the possible negative impacts on incentives to innovate, and to allocate capital to the EU, of the adoption of new regulatory, largely untried principles, primarily the test of 'essentiality', to manage the risks posed by the use of technologies and the development of new ones.[5]

In view of this, this proposed Recommendation sets out a robust basis to further trigger improvements in the way in which governments use the principles and mechanisms of Better Regulation to strengthen incentives for the private sector to invest in innovation.

In particular the following ideas, included in the Draft Recommendation, are to be welcomed and should shape future regulatory policy by OECD members, including the European Union and its Member States:

- **Innovation** is a key driver of economic prosperity and change, and will play a fundamental role in helping citizens achieve social, economic, and environmental goals in the future;

- **Private sector** businesses, investors, and risk-takers play a central role in developing and disseminating innovative ideas, leading to new and improved products, services, operating models, and ways of doing business. Public policy, including regulation, should recognise this;

- Regulations, and the institutions and processes used to implement them, are an important part of the **framework conditions** that determine incentives to innovate and to allocate capital;

- Regulators, when developing new measures or assessing the effectiveness of existing ones, should explicitly assess the impact of regulations on innovation. This is a recognition, albeit implicitly, of the value of embedding the **Innovation Principle**[6] in regulatory governance and in regulatory management tools;

- Regulatory policies for managing the impacts and facilitating the benefits of new technologies should focus on **outcomes**, rather than prescriptive rules, and should use voluntary standards or guidance in place of rigid command-and-control laws. These recommendations begin the process of putting in place a formal policy for new technologies designed to encourage innovation rather than slowing down access to markets or distorting technological pathways;

- When assessing the impact of regulations on innovation, regulators should use regulatory management tools to assess the consequences of measures on **value chains**. This recognises the complexity of modern economies, the role that platform technologies (such as those embedded in metallic chemicals or life sciences) play in facilitating innovation in

[3] See ERIF Highlights Note 2 on Hazard-based Regulation.

[4] See ERIF Monograph on the EU Administrative State.

[5] See ERIF Highlights Note 16 on Essentiality.

[6] See ERIF Monograph on the Innovation Principle.

downstream applications, and the complex ways in which consumer brands create value for citizens and economies;

- Regulatory management tools should be applied and integrated throughout the policy-making cycle, placing particular importance on an enhanced role for **ex post evaluation**. When used well, ex post evaluation can identify emerging or embedded regulatory obstacles to innovation, as well as highlighting other forms of regulatory failure. Removing obstacles, created by the regulatory framework or the processes and institutions used to implement it, should play an important part in a well-designed regulatory policy for innovation. It is one of the ways of enhancing incentives to innovate;

- When assessing the intervention logic for measures designed to manage the development or use of technologies, regulators should focus on risks, the **likelihood of harm**, and a credible assessment of the **benefits** of intervention, rather than hazardous properties. If this process is underpinned by high quality scientific evidence, that meets accepted standards of **scientific integrity**, then it reduces regulatory uncertainty, thereby strengthening incentives to allocate capital and to invest in innovation.[7];

- Regulatory co-ordination across all levels of government, including **agencies**, should be strengthened. This recognises, implicitly, the impact of implementation processes and the actions of the **Administrative State**, on incentives to innovate. Insufficient attention has been paid by policy-makers to this phase of the regulatory cycle;

- **Regulatory oversight bodies** should be granted additional powers to scrutinise proposed measures so as to ensure that their impact on innovation has been fully and properly assessed. This will further increase the focus, within governments, on understanding links between innovation and the regulatory framework; and

- **International regulatory co-operation** should be strengthened. One way in which this can deliver practical benefits for regulators is through the sharing and adoption of good practices, particularly the development of policies and regulatory management tools. Information about regulatory obstacles can also be shared, along with benchmarking data to allow regulators to compare implementation processes and mechanisms.

Finally, the Draft Recommendation provides a powerful endorsement of the fundamental principles of evidence-based decision-making, and of the regulatory management tools used to deliver it. This commitment should be endorsed by all OECD members.

[7] See ERIF Communication 20 on Scientific Integrity Principles.

3. RECOMMENDATIONS AND GUIDANCE – SPECIFIC COMMENTS

3.1. Recommendations

Whilst in overall terms, the draft recommendations represent an important contribution to the OECD's approach to regulatory policy, it is suggested that they could be improved with a small number of amendments:

- **Overall Objectives** – the recommendations should be revised to clarify their overall purpose and to strengthen the focus of regulators on unlocking the benefits of innovation. More emphasis should be placed on the role that regulatory management tools can play in identifying ways to increase incentives to innovate and to remove obstacles, thereby enabling citizens to enjoy the benefits of new or improved ideas whilst ensuring a high standard of protection for man and nature.

- **Innovation Principle** – OECD members should adopt this regulatory principle as part of improving the focus of regulators on the relationships between regulations, and their implementation, and innovation. The adoption of the Innovation Principle will also help shape the regulatory culture within governments.

- **Regulatory Policy and Innovation** – the recommendations should be expanded to encompass four additional aspects, alongside outcomes-based rules and use of voluntary standards. OECD members should adopt regulatory policies for innovation that include the following additional requirements: regulations should be technologically neutral, such that technologies are not stigmatised; second, safety rules should focus on specific applications not technologies, be based on risk rather than hazard, and be informed by scientific evidence that meets the highest standards of scientific integrity; third, incremental innovation should be supported, as well as breakthrough ideas; and, finally, regulations should maximise opportunities for investors and entrepreneurs to compete.

- **Discretion, Property Rights and Allocation of Capital** – the recommendations should be revised so as to remind regulators that administrative discretion creates uncertainty and that basing regulatory approval of actions by private sector actors on derogations, exemptions or experimentations does not create adequate property rights. Weak or non-existent property rights undermine incentives to allocate capital to investment in innovation. Increasing regulatory uncertainty, because of the need to make complex trade-offs, has the same effect. Competition and access to market may also be hampered. These caveats should be included in the recommendations.

- **Ex post evaluation and regulatory obstacles to innovation** – the recommendations should be expanded to highlight the role that ex post evaluation can play in identifying regulatory obstacles to investment in innovation. As a regulatory management tool, it is of particular importance in identifying horizontal (cross-sectoral) problems such as Defensive R&D,[8] and obstacles, such as increased time-to-market and capitalised development costs,[9] created by the way in which regulations are implemented.

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[8] See ERIF Highlights Note 8 on Defensive R&D and Innovation.

[9] See ERIF Highlights Note 15 on 'Time-to-Market' and Innovation.

3.2. Guidance

The provision of a comprehensive guidance document to aid OECD members as they seek to implement the recommendations is to be welcomed. Many of the ideas are insightful and useful.

However, in a small number of areas, we suggest that the guidance be expanded or revised. Specifically:

- **Overall focus** – the guidance focuses primarily on radical innovation, and on 'breakthrough' advances in digitalisation. It is important to recognise in the guidance that incremental innovation in more 'traditional' sectors, based on exploiting existing ideas or combining ideas, can also substantially drive prosperity and help citizens achieve social, economic, and environmental goals. Moreover, the guidance points to start-ups and SMEs as the 'target' private sector actors in the innovation ecosystem. Whilst these businesses are important, the guidance should recognise explicitly the important role that large-scale enterprises play in developing and disseminating new or improved products, services, operating methods, and ways of doing business. They are, for example, the most important source of expenditure on R&D and may also work with smaller enterprises in complex innovation networks.

- **Links between regulation and innovation** – there is insufficient emphasis on the links between innovation and the regulatory framework. The guidance should be enhanced, possibly using a framework conditions model, to help regulators understand these linkages. For instance, the guidance could focus on regulatory impacts on social attitudes, market conditions and access to markets on the 'demand-side' of the model, and on the critical inputs of access to capital, labour, ideas, and digital infrastructure on the 'supply-side'. Guidance should reflect the positive and negative role that regulations, including implementation, play and could draw on cross-sectoral knowledge.

- **Allocation of Capital, Regulation, and Innovation** – the guidance should recognise that regulations, and the way in which they are implemented, affect the allocation of capital by investors and large companies and hence the scale and nature of investment in innovation. It should suggest to regulators that when they are designing regulatory management tools they should ensure the following factors are addressed explicitly: property rights, access to markets (including time to market and restrictions on the 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. This could take the form of the adoption of an "allocation of capital test".

- **Science, Data, and Evidence** – the guidance places considerable emphasis on the potential role that advances in (Big) Data capture, processing, and interpretation could play in helping regulators anticipate potential harms and to identify when regulations are failing to deliver benefits. Whilst this is a potentially important source of evidence, the guidance should be expanded to recognise the continued importance of science and traditional scientific assessments. This will continue to be the primary source of evidence underpinning regulatory decisions particularly for risk management measures. Regulatory science should rest on the Scientific Method and on established causality linkages between exposure and harm.

  In the light of this, the guidance should encourage OECD members to establish robust processes and structures to ensure that scientific evidence, and the assessment processes used to develop it, meets the highest standards of scientific integrity. Processes should also ensure that scientific evidence is impartial and excellent. To achieve these goals, OECD members need to develop new processes for selecting scientific advisors and managing scientific assessments that reflect modern understanding of bias and of the wide range of conflicts-of-interest that cause it. Finally, the guidance should highlight the importance for regulatory certainty, a requirement for the allocation of capital, of basing regulations on the highest quality scientific evidence.[10]

- **Co-ordination and implementation of regulations** – the guidance should be expanded to draw the attention of OECD members to the impact of implementation processes and mechanisms on incentives and obstacles to invest in innovation.

  Research by ERIF identified major failings of governance and a mismatch between resources and the scope of responsibilities entrusted to the EU's Administrative State.[11] These contribute to a significant risk of implementation decisions failing to meet global standards of regulatory quality. Indeed, the ERIF report concluded that 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.

  To overcome these problems, the guidance should suggest that OECD members implement a series of reforms including adopting a comprehensive Law of Administrative Procedures; establishing common standards for scientific integrity; systematically applying the Proportionality Principle; and ensuring that substantive guidance, standards, and secondary legislation fall within the scope of regulatory management tools.

- **Emerging regulatory obstacles to incentives to invest in innovation** – the guidance should be expanded to encompass the role that regulatory policies and management tools can play in identifying and understanding the impact on incentives to innovate of new or emerging regulatory principles.

  Basing regulatory decisions on hazard, often combined with mandatory substitution, rather than risk (likelihood of harm) has become increasingly influential as a means of managing harms in parts of the OECD area. Its negative impacts include loss of access to technologies, increased regulatory uncertainty, and risk-risk trade-offs.

  Within the EU, for instance, this approach has been developed further to possibly encompass the adoption of various tests of 'essentiality' to replace application-specific assessments of the likelihood of harm. Indeed, this might lead to potentially banning application on the basis of grouped assessments of hazard characteristics apart from those deemed to be 'essential' by the regulator. Potential negative consequences include systemic regulatory uncertainty, loss of markets, loss of access to technologies, and undermining of property rights. All undermine incentives to allocate capital. The guidance should be expanded to show how these issues should be identified.

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[10] See Footnotes 2, 3 and 7 above.

[11] See ERIF Monograph on the EU Administrative State.

- **Enforcement of regulation and corporate 'values'** – the guidance proposes that enforcement of regulations by governments should take into account the 'values' of affected entities, as well as the risk of non-compliance based on traditional objective factors. This idea should be removed from the guidance. It is not consistent with traditional, Western understandings of the concept of the "rule-of-law". Laws should apply equally: their enforcement should not depend on the empathy, or otherwise, of officials, for subjective views expressed by affected entities. Adherence to the concept of the rule-of-law is one of the most important factors that determines whether or not capital will be allocated to markets.

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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 Communication. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the ERIF or its members.

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