European Risk Forum – Communication 19

Strengthening the EU's Better Regulation Strategy: Ideas from the European Risk Forum

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1. Foreword

It is with great pleasure that we take this opportunity to share with you the ERF's ideas for strengthening the European Union's Better Regulation strategy. Our contribution to the Commission's recent consultation recognises the immense progress that has been made to establish a modern approach to making and implementing laws. This is to be welcomed.

But more needs to be done to build on this so as to achieve all of the possible benefits of good regulation. In our extensive contribution, you will find an extensive analysis of the progress made by the Commission and detailed recommendations for improvement. Our ideas cover issues such as impact assessment, consultation, ex post evaluation, the use of scientific evidence in decision-making, continued access to eminent experts, risk management strategies, and dynamic impacts of regulation, including links between risk management and incentives to innovate.

We hope that you will find our ideas to be of interest and that they may contribute to your efforts to inform the development of a world-leading process for making and implementing laws at EU-level.

Howard Chase
Chairman
European Risk Forum

Dirk Hudig
Secretary General
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Executive Summary

Background

This is a contribution by the European Risk Forum (ERF, www.riskforum.eu) to the public consultation launched by the European Commission on *"Stocktaking of the Commission's 'better regulation' approach"*. The purpose of the public consultation is to engage citizens and stakeholders with a view to enrich the appraisal of how well the various better regulation tools used by the Commission work in practice and contribute to achieving the objectives of its better regulation policy. The ERF welcomes the opportunity to comment on this matter and expresses its full support for the efforts made by the European Commission in particular, along with the other EU institutions, to sustain the efforts to consolidate, refine and upgrade good regulatory practices throughout the decision-making at the EU-level.

Overall Comments

For almost two decades now, the European Commission has invested in the development of one of the largest regulatory management programmes in the world. Policies have been established; process management standards have been created, covering impact assessment, consultation, and ex post evaluation; and new Better Regulation institutions have been set up, including a formal oversight body and arrangements for scientific advice.

Evidence from a number of independent expert studies suggests that the Better Regulation Strategy of the European Commission outperforms equivalent initiatives in most OECD and EU countries. As such, the European Commission has become a driving force for mainstreaming good regulatory principles, governance and practices between the EU institutions and among EU Member States. The Commission has established itself at the forefront of not only implementing the Better Regulation agenda but also of meeting the agenda's new frontier, acting as a thought- leader for more responsive and innovative solutions.

The ERF therefore congratulates the European Commission for the developments introduced so far. They constitute a robust basis to consolidate the commitment for 'better regulation' and further enhance the reform.

ERF Recommendations

General

Within this context of successful improvement and considerable progress, the ERF has identified a series of additional reforms that could, if implemented fully, further strengthen the EU's position as one of the world's leaders in regulatory management and governance.

Our specific recommendations cover regulatory process management tools and a group of important cross-cutting regulatory themes. Amongst the most important issues highlighted by the ERF are the following:

- Strengthen the integrity of scientific evidence used to guide the policy cycle;
- Develop new ways to manage bias, by focusing on the complex material and non-material (ideologies, beliefs, ideals, political commitments) conflicts-of-interest that cause it, thereby maintaining access to the most eminent and relevant scientific experts;
- Encourage greater focus on the principle of proportionality when designing interventions and implementing laws;
- Understand the importance of using risk, rather than hazard, to manage the potential harms posed by technologies or lifestyle choices;
- Use existing best practices to improve the functioning of risk assessment agencies;
- Highlight the need to assess rigorously the costs and effectiveness of interventions based on the use of substitution, and other similar novel and untested strategies, as a risk management tool;
- Require risk assessors to draw clear distinctions between scientific evidence based on real life conditions and that based solely on hypothetical exposure or laboratory conditions; and

- Focus on designing risk management measures that are technologically-neutral, thereby regulating products rather than technologies, and strengthening incentives to invest in innovation.

Regulatory Process Management – Suggested Reforms

Ex Ante Impact Assessment

- Require the responsible Commission services of Secretariat General to provide a comprehensive justification explaining why an Impact Assessment has not been carried out;

- Expand the scope of the IA process to encompass fully the implementation of laws by the EU's Administrative State;

- Enhance requirements to apply the principle of proportionality when designing interventions;

- Require officials to consider explicitly problems of overlap, conflict and coherence when designing new regulatory interventions;

- Strengthen requirements to quantify the outcomes of new interventions and to include clear performance metrics;

- Develop additional guidance to strengthen the focus on understanding the impact of proposed interventions on the creation and protection of intangible assets; and

- Ensure that draft Impact Assessments are made available publicly for 'notice-and-comment' scrutiny.

Stakeholder Engagement

- Introduce mandatory, legally binding due process standards regulating public consultation;

- Systematically include all major implementing decisions by the Commission and the EU agencies under the scope of the Commission's minimum standards for consultation;

- Require all draft IAs to be published and subject to public consultation prior to the development of a final proposal, adhering to the Commission's minimum standards for stakeholder consultation;

- Strengthen the distinction between the gathering of evidence and the consultation process, especially for risk management measures, and formally recognise that they are not equivalent; and

- Limit the dependence on (online) closed question, multiple choice questionnaires.

Ex Post Evaluation

- Establish a greater range of strong 'evaluation triggers', including a requirement for the inclusion of a binding review clauses whenever risk management decisions are justified by the use of the Precautionary Principle;

- Broaden the scope of evaluations, practices and methodologies to encompass all major implementation decisions;

- Clarify the type of evaluation, so that the purpose of the exercise is transparent and guides activity;

- Establish quality standards for the evidence to be used to support evaluation exercises within the Commission;

- Harmonise standard values, methodologies, and approaches used across sectors and over time;

- Enhance data collection and monitoring coordination for implementation and compliance with EU legal and regulatory decisions;

- Up-grade the capacity of the ex post evaluation system to draw 'horizontal' policy lessons from individual evaluations ('horizontal' added-value); and

- Utilise the findings of ex post evaluations to support the sharing of best practices amongst EU agencies.

Regulatory Oversight

- Widen the scope of the Regulatory Scrutiny Board to include the implementation of risk management decisions by legal, administrative and other mechanisms;

- Expand the mandate of the Regulatory Scrutiny Board to encompass oversight of the quality of scientific evidence used to justify interventions; and

- Require opinions of the Regulatory Scrutiny Board to be published as soon as they are adopted.

Improvement Themes – Suggested Reforms

Objectives of Better Regulation

- Develop a new set of political commitments and objectives for the Better Regulation Agenda that strengthen commitments to base decisions on evidence and to use regulation to promote innovation;

- Include in a revised Better Regulation Communication a specific political commitment to use the regulatory process to promote investment in innovation;

- Make the Better Regulation Guidelines a formal political commitment;

- Revise the Better Regulation Guidelines to require all interventions to demonstrate that benefits justify costs and that the least restrictive means of achieving the regulatory goal has been employed;

- Strengthen the requirement, set out in the Better Regulation Guidelines, to base interventions on the best available evidence, by requiring adherence to explicit quality standards and by including it in the Better Regulation Communication; and

- Expand the Better Regulation Communication and Guidelines to require officials to ensure that new and existing interventions are proportionate and coherent with other parts of the regulatory framework.

Management of Risk

- Develop and adopt common principles and minimum detailed standards for risk analysis;

- Expand the guidelines for impact assessment and risk management to recognise that the intervention logic for ex ante assessment of measures designed to manage risks posed to human health, public safety, and the environment should be based on the findings of a formal science-based risk assessment;

- Base interventions on a proportionate assessment of the risk of exposure, rather than the hazard of intrinsic properties;

- Require measures designed to protect human life, public safety, or the environment to re- assess the original scientific evidence and risk assessment used to justify intervention, as well as examining new scientific evidence, within an appropriate time horizon;

- Revise the guidance to emphasise that risk management decisions based on the Precautionary Principle are limited to certain, specific circumstances where data is missing;

- Highlight the need to ensure that all policy interventions designed to manage risks include a clear statement of measurable final outcomes, intermediate behavioural changes, and actions by affected parties;

- Recognise explicitly that knowledge, derived from the scientific method and meeting internationally-accepted standards of quality, should be the pre-eminent form of evidence used for managing risks;

- Require scientific studies that are used to justify regulatory interventions to be available for public review, to meet the standards of the scientific method, to subject to transparent peer review, and to have validated protocols, that make the tests capable of being replicated by other researchers; and

- Expand the guidelines to include a series of specific additional requirements to be met when using impact assessment tools to assess potential risk management interventions.

Science and Evidence – General

- Rest political responsibility for the quality and effectiveness of the overall process of collecting and using scientific evidence to make risk management decisions with the First Vice-President in charge of Better Regulation;

- Establish formal central oversight with responsibility for ensuring the effective functioning of the entire scientific advisory system;

- Develop and adopt, in, for example, a new European Commission Decision, minimum standards for the quality, collection, validation, and use of scientific evidence that all directorates and agencies must respect;

- Revise standards and processes for public consultation to recognise the difference between opinions collected through such processes and the outcomes of scientific assessments;

- Develop supplementary guidelines that clarify the application of the Precautionary Principle in regulatory decision-making; and

- Require the Regulatory Scrutiny Board to ensure that all sections of ex ante impact assessments fully meet the relevant requirements set out in the Better Regulation guidelines.

Science and Evidence – Access to Expertise

- Set out the key principles for the selection of scientific experts and for the operation of scientific committees in, for instance, a new Commission Decision.

Dynamic Impacts of Regulation

- Revise the 'Competitiveness' guidelines (Sectoral Competitiveness Tool #20) to encourage a greater focus on operating efficiency rather than costs;

- Expand the 'Competitiveness' guidelines (Sectoral Competitiveness Tool #20) to require officials to consider a rigorous examination of adjustment costs when examining interventions;

- Improve the 'Innovation' guidelines (Research and Innovation Tool #21) to highlight the need for officials to consider impacts of innovation on a wider range of framework conditions, including social attitudes, access to markets, and access to key inputs (ideas, people, capital, and infrastructure);

- Expand the 'Innovation' guidelines (Research and Innovation Tool #21) to encompass an explicit recognition of the value and importance of considering the Innovation Principle when designing interventions;

- Enhance the 'Competitiveness' guidelines (Sectoral Competitiveness Tool #20) by increasing the range of specific regulatory impacts that should be considered by officials by adding capitalised costs of development, technology choices, stigmatisation, use of hazard-based measures, and regulatory coherence; and

- Strengthen the 'Innovation' guidelines (Research and Innovation Tool #21) by requiring interventions to avoid regulating new technologies specifically and to focus instead on the products they generate that have a specific impact on society.

Implementation of Risk Management Laws and the Administrative State

- Work with the European Parliament to develop and adopt a comprehensive Law of Administrative Procedures;

- Revise the Better Regulation integrated guidelines to strengthen further the focus on Implementing and Delegating Acts (the revised forms of comitology);

- Require all legal implementing measures that ban or restrict the use of a substance or technology to undergo a comprehensive impact assessment, including the impacts of substitution and substitutes;

- Expand the scope of the Better Regulation integrated guidelines to include all substantive guidance developed by the EU's risk assessment agencies;

- Expand the remit of central quality oversight of the Regulatory Scrutiny Board to encompass all of the processes used to implement proportionate risk management legislation; and

- Require the EU's risk assessment agencies to develop a set of formal best practice standards for the development of substantive guidance, where these have the effect of influencing behaviour of affected parties.

European Risk Forum
October 2018

1. Introduction

This is a contribution by the European Risk Forum (ERF, www.riskforum.eu) to the public consultation launched by the European Commission on *"Stocktaking of the Commission's 'better regulation' approach"*. This ERF Communication complements the ERF response to the online questionnaire underpinning the public consultation.[1] The public consultation is open for public comments from 17 July 2018 to 23 October 2018.

The purpose of the public consultation is to engage citizens and stakeholders with a view to enrich the appraisal of how well the various better regulation tools used by the Commission work in practice and contribute to achieving the objectives of its better regulation policy. These tools include evaluation of existing policies and programmes, impact assessment, and stakeholder consultation.

The European Commission invites the public to specifically focus on the changes introduced and/or updated by the better regulation package of May 2015 – namely: evaluation, impact assessment, stakeholder consultation, the Regulatory Scrutiny Board, the REFIT Platform and the REFIT Programme. The exercise should highlight the strengths and weaknesses of the current system and identify areas for improvement.

The ERF welcomes the opportunity to comment on this matter and expresses its full support for the efforts made by the European Commission in particular, along with the other EU institutions, to sustain the efforts to consolidate, refine and upgrade good regulatory practices throughout the decision-making at the EU-level.

This ERF Communication is structured in four parts:

- Section 2 provides a general assessment of the overall approach taken to Better Regulation by the European Commission;
- Section 3 considers each of the main regulatory management tools in details, highlighting fundamental success factors as well as individual elements that deserve further refinement;

1 See https://ec.europa.eu/eusurvey/runner/StocktakingBetterRegulation.

- Section 4 addresses six cross-cutting improvement themes which, in the opinion of the ERF, would, if implemented, substantially contribute to making the EU decision-making process more predictable, effective and proportionate during the next Commission's term and beyond; and

- Section 5 sets out brief conclusions.

2. General Comments

2.1. Better Regulation for Modern Government

Modern government must take account of and contribute to shaping the 21st Century world. Economies and societies are characterised by faster interactions between various actors across several levels of governance. Regulators are called upon to tackle increasingly complex and multi- faceted challenges. Whereas in the past problems have tended to be tackled singularly as definite entities, today societies recognise the presence of, and expect solutions to, risks that range from the systemic and the 'macro' dimensions, to the individual and the 'micro'.

Public opinion influences the salience of policy issues. Citizens have higher expectations of the capacity of governments to solve problems, but at the same time, and paradoxically, lack confidence in public institutions and decision-making. Objective and calm assessment of facts has, moreover, become more difficult because of pervasive relativism and distrust in expertise.

In response to this contemporary context, governments have embarked on a series of structural reforms of the public sector. Better Regulation strategies are, in most countries in the OECD area, a part of such endeavours. In general, they seek to **establish decision-making processes that meet the needs and expectations of citizens, including businesses, in the most legitimate, proportionate and cost-effective manner, while recognising and limiting unintended consequences.** To be successful, there must be a structured, dynamic and consistent effort to improve the quality of decision-making processes and the resulting public policy interventions.

Better Regulation recognises the central role that regulation plays in modern society. At its best, regulation strengthens legitimacy and consent, ensures that social aspirations are met and, at the same time, creates a context that encourages investment and innovation. If well designed and implemented, Better Regulation strategies help achieve inclusive growth, prosperity and sustainability.

Challenges to design and implement Better Regulation principles and accompanying good regulatory practices nonetheless persist in all OECD countries. Societal goals are often contradictory and not properly translated into traditional legislative and rule-making processes. Many of the powers of the State are, increasingly, delegated to agencies or officials, stretching technical and rule-making expertise to its limits. Regulations frequently overlap or conflict, as new rules designed to combat new concerns are added to existing, established legal frameworks.

Within this context, regulatory failure is widespread. All too often, regulations fail to achieve their goals or create unintended consequences, such as additional risks or less innovation. Legitimacy is undermined as well, if the development of regulations fails to meet modern standards of governance.

The ERF considers Better Regulation – and in particular high-quality risk assessment and risk management decisions – as being in the public interest, and of critical importance for European competitiveness.

2.2. The European Commission: A Leading Force in Regulatory Reform

For almost two decades now, the European Commission has invested in the development of one of the largest regulatory management programmes in the world. Policies have been established; process management standards have been created, covering impact assessment, consultation, and ex post evaluation; and new Better Regulation institutions have been set up, including a formal oversight body and arrangements for scientific advice.

Evidence from a number of independent expert studies suggests that the Better Regulation Strategy of the European Commission outperforms equivalent initiatives in most

OECD and EU countries.[2] **A series of positive features have been identified and acknowledged:**

- *Comprehensive*, it encompasses the entire life-span of an EU initiative and it includes tailored tools and arrangements for the various phases of the 'policy cycle';

- **Institutionalised**, all of the regulatory management tools included in the Better Regulation Strategy are integrated into the procedural and organisational modus operandi of the Commission services (DGs) and, moreover, their application is designed synergistically;

- **Inclusive**, compatible and open to coordination with the reform strategies of the other EU institutions and, possibly, those pursued by the EU Member States;

- **Underpinned** by adequate resources and capacities, especially in terms of the general level of the expertise available, when compared to many nation states within the OECD area;

- **Sustained** over several Commission terms, thereby stimulating good practice sharing and institutional learning;

- **Scrutinised publicly,** thanks to a rich public debate prompted by regular stakeholders' position papers as well as formal reviews and assessments by the EU institutions and advisory bodies;[3] and

- **Evolved** over time, signalling commitment to continuous improvement, complementing and refining the various components of the strategy over time.

As such, the European Commission has become a driving force for mainstreaming good regulatory principles, governance and practices between

2 Cfr., among other, the OECD Regulatory Policy Outlook 2018, at https://www.oecd.org/governance/oecd-regulatory-policy-outlook-2018-9789264303072-en.htm.

3 Among recent formal evaluation of (elements of) the Commission Better Regulation strategy count inputs from European Parliament, the European Court of Auditors, the Economic and Social Committee, the Committee of the Regions, the Regulatory Scrutiny Board, as well as various task forces.

the EU institutions and among EU Member States. In many independent assessments, the Commission has established itself at the forefront of not only implementing the Better Regulation agenda but also of meeting the agenda's new frontier, acting as a thought-leader for more responsive and innovative solutions.

The Better Regulation 'package' launched by First Vice-President Timmermans in 2015 and updated last year builds on such a positive appraisal. The ERF considers the latest developments introduced by this Commission to be a major step forward compared to previous approaches.

More than in the past, the package:

- Focuses on governance, presenting the Better Regulation Strategy as essential for delivering the social and economic policies of the European Union;
- Elevates the importance of consultation with stakeholders within the regulatory process, recognising its importance for the quality and legitimacy of decisions;
- Strengthens scrutiny, establishing a new oversight institution (the Regulatory Scrutiny Board) with a wider remit, greater resources, and more involvement of external experts than its predecessor;
- Integrates all existing regulatory management standards, creating a seamless, consistent, and coherent approach throughout the policy cycle; and
- Recognises the role that good regulation can play in driving up productivity, wages, and living standards. Competitiveness impacts, including changes in incentives to innovate, must now be considered at all times, for instance.

The ERF therefore congratulates the European Commission for the developments introduced so far. They constitute a robust basis to consolidate the commitment for 'better regulation' and further enhance the reform.

2.3. The Need for Constructive Cooperation

On the other hand, it is clear that, if the reforms are to be effective and societal aspirations are to be met, then prompt and constructive co-operation will be required from all of the actors participating and benefitting from policy-making.

Accordingly, the ERF also invites the European Parliament, the Council of the European Union as well as the EU Member States to also take stock of their respective Better Regulation strategies, opening them to public contributions for possible improvements and, on that basis, advance the reforms along establish good international practices.

At the EU level, the co-legislators must take a lead. While the European Parliament has already made significant progress, the Council has yet to demonstrate full 'ownership' of the Better Regulation agenda. Initial measures have been introduced for a more transparent evidence-based approach to Council deliberations (for instance with the launch of a system for assessing significant impacts), but many fundamental elements of the Inter-Institutional Agreement on Better Law- making are yet to find systematic implementation.

Member States must give support too. The 'traditional narrative', advocating Better Regulation as a device for reducing red tape, administrative burden, and direct compliance costs, must be complemented by one grounded in a better understanding of the scope and nature of modern regulation and its impacts. Issues of governance must be given greater prominence too, thus making national decision-making processes more open and reinforcing capacity-building initiatives. And, it needs to be recognised that the quality of regulation is often more important than the quantity.

In their turn, affected entities – private sector operators and civil society organisations alike – will need to modernise their approach. They will need to invest in developing tools to help regulators make good decisions, contributing constructively to the policy debate on the basis of robust, rigorous expertise. Sectoral socio-economic analyses should be carried out, showing the public benefits of private sector economic activities, of technologies and of value chains. Analyses should also better highlight the impact of the current regulatory framework on the competitiveness of European industry, and hence on its ability to deliver wider benefits to Europe and its citizens.

3. Regulatory Process Management

This section shortly reviews the main features and the recent development of key regulatory management tools, as outlined in the Commission 2015-2017 Better Regulation 'package'. The tools considered are:

- Ex Ante Impact Assessment (Section 3.1.);
- Stakeholder Engagement (Section 3.2.);
- Ex Post Evaluation (Section 3.3); and
- Regulatory Oversight (Section 3.4.).

3.1. Ex Ante Impact Assessment

3.1.1. Background

From its outset in 2002, ex ante Impact Assessment (IA) has been a cornerstone of the Better Regulation agenda of the Commission. Over time, the Commission has maintained the same basic features of the tool, which to a great extent make it amongst the most complete and well-embedded system in use in the OECD area. Specifically, those features are:

- **Integrated approach** – it remains a distinctive feature of the Commission's approach to consider all three categories of impacts (the economic, social and environmental dimensions) in a single tool and IA process. This avoids narrowing the evidential analysis of regulation to mechanistic calculations of selected administrative burdens or confining it to compartmentalised 'tests'. The Commission approach to IA reinforces policy integration and invites the investigation of synergies and trade-offs;
- **Early notice and publicity** – the publication of roadmaps on a single web-portal is critical for notifying stakeholders and the public early on about forthcoming initiatives and ideas for possible intervention. This not only prompts reactions from third parties

but also allows stakeholders to organise internal mechanisms for data collection and elaboration of positions;

- **Tailored efforts** – ensuring appropriate targeting and proportionality in the resources (time and expertise) deployed to analyse policy proposals and their possible impacts is essential to maximise the added value from carrying out IAs on priority projects and avoid deadlocks and resistance because of perceived excessive burden on other projects. The IA system is well synchronised with the planning and work programme of the Commission. The intranet-platform 'Decide' allows for identifying, screening and managing the flow of initiatives in line with the Political Guidelines of the President.[4] The Work Program is then published[5] and structured along tailored assessments – from roadmaps and Inception IAs to full IAs;

- **Internal coordination** – IAs and, increasingly, ex post evaluations are discussed in interservice groups chaired by the Secretariat-General. The inter-service consultation occurs not only on the text of the proposal but also on the underpinning analyses. Such a systematic involvement of all relevant services enriches the evidential analysis and the types and accuracy of the data used to underpin decisions, and it enhances policy integration; and

- **Enhanced guidance** – over time, the guidance made available to IA drafters and policy analysts has been significantly upgraded thanks to the detailed Toolkit elaborated in 2015 and updated in 2017 as a complement to the Better Regulation guidelines. This allows for progressive sophistication of the expertise and sets the basis for a more thorough and robust understanding of the relevant likely impacts of the initiatives. In particular, the new requirements and ideas set out in IA Toolkits #20 and #21 on 'Sectoral Competitiveness' and 'Research and Innovation', are to be welcomed. The Directorate-General for Research and Innovation has established a dedicated Task Force and piloted the implementation of the latter toolkit on several Commission proposals, thereby promoting a more attentive consideration of the impacts of interventions on innovation.

4 See https://ec.europa.eu/info/sites/info/files/better-regulation-guidelines-planning.pdf.

5 See https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law_en.

3.1.2. Areas for Improvement

The European Commission's IA process is one of the largest and most advanced in the OECD area. This reflects a commitment to progressive reform, informed by experience and dialogue with stakeholders, since its introduction in 2002. This is to be welcomed.

Despite this, more needs to be done to strengthen further the IA process. It remains based, conceptually, on a traditional legislative model, whereby laws are made by the EU institutions and implemented by Member States. Today, many of the most important economic and social interventions take place through the operation of the EU's Administrative State. This is not reflected in the design and scope of the EU's IA process.

A further problem is that the IA process fails to recognise adequately the maturity and complexity of the EU's legislative and regulatory framework. New interventions, unless carefully designed, conflict with and overlap existing requirements, leading to a lack of regulatory coherence and unintended negative consequences. If ex post evaluation mechanism function well, maturity of regulatory experience also provides regulators with the opportunity to consider rigorously the strengths and weaknesses of different strategies for achieving policy goals. This needs to form part of the IA process.

Finally, the overall approach to assessing the impacts of prospective interventions needs to place greater emphasis on the way in which many modern businesses create value, and hence deliver the products and services that benefits citizens and societies. Today, intangible assets are often the primary driver of value creation. A cutting-edge IA process should recognise this.

3.1.3. Reforms

Key ERF recommendations:

- **Require the Secretariat General to provide and publish a comprehensive justification explaining why an IA has not been carried out** – the Regulatory Scrutiny Board should issue an opinion commenting on the decision by the Commission not to carry out an IA. This opinion should be published in a timely manner;

- **Expand the scope of the IA process to encompass fully the implementation of laws by the EU's Administrative State** – this should include that all phases of the policy cycle are fully integrated into the Commission's Better Regulation agenda. (See Section 4.6 for a more extensive analysis and a set of suggested reforms.);

- **Enhance requirements to apply the principle of proportionality when designing interventions** – this will help improve the effectiveness and legitimacy of EU action;

- **Require officials to consider explicitly problems of overlap, conflict and coherence when designing new regulatory interventions** – this should help to develop a greater degree of integration of the EU's mature legislative framework, as well as ensuring that laws support wider policy goals;

- **Strengthen requirements to quantify the outcomes of new interventions and to include clear performance metrics** – this should encompass initial activities by affected entities and government ('input measures'), behavioural changes anticipated ('intermediate outcomes') and final benefits ('outcomes measures'). More emphasis on performance measurement will strengthen the links between the intervention logic and the justification for state action. It will facilitate ex post evaluation. And, it will strengthen legitimacy by demonstrating that benefits justify costs;

- **Develop additional guidance to strengthen the focus on understanding the impact of proposed interventions on the creation and protection of intangible assets** – this should include all forms of intangibles, recognising their critical role in supporting innovation and underpinning operating efficiency, in creating value, and in meeting the needs of customers and societies. Guidance should define intangibles widely encompassing assets such as patents, trademarks, copyrights, trade secrets, business models, and confidential business information; and

- **Ensure that draft IAs are made available publicly for 'notice-and-comment' scrutiny** – this should improve the completeness and accuracy of the examination of costs and benefits and facilitate examination of the robustness and credibility of the intervention logic underpinning the proposed intervention.

3.2. Stakeholder Engagement

3.2.1. Background

Stakeholder engagement is an essential part of modern decision-making. The European Commission public consultation process meets many of the good practices for effective consultation identified by the OECD, including seeking plain language communication, setting minimum consultation periods, and providing meaningful feedback on consultation findings.

From the adoption of the Better Regulation package in 2015, the Commission has introduced important positive developments, most notably:

- **User-friendly, interlinked websites** – the Commission ensures user-friendly access to the two interlinked portals it administers. The so-called "Have your say" portal explicitly invites the public to contribute ideas and provide feedback on initiatives to be launched at the EU level. It is complemented by the website dedicated to both open and closed consultation. Both allow users to search specific initiatives and to register for timely personalised notifications.[6] The channels for stakeholders' inputs have been expanded also in relation to the work of the REFIT Platform, in particularly through the launch of the 'Lighten the load' portal;[7] and,

- **New consultation periods** – the Commission acknowledges the importance of opening up the decision-making process. It has expanded the mandatory minimum consultation period 12 weeks for initiatives with IA (plus 8 weeks on adopted legislative proposals); it has introduced a 4-week "feedback consultation" on Roadmaps for evaluations and fitness checks, and roadmaps and inception IAs; and allows 4 weeks for draft delegated acts and implementing acts of general application and draft measures following the regulatory procedure with scrutiny.

6 See https://ec.europa.eu/info/law/better-regulation/have-your-say_en and https://ec.europa.eu/info/consultations_en, respectively. In addition, the 'Legislative Observatory' portal managed by the European Parliament allows the public to track procedures and monitoring the EU decision-making process (http://www.europarl.europa.eu/oeil/home/home.do)

7 See https://ec.europa.eu/info/law/better-regulation/lighten-load_en.

The integration of the consultation and the IA is particularly developed. Public consultation rounds take place regularly along the policy and legislative cycle, including on early assessments.

3.2.2. Areas for Improvement

A number of challenges to the practical implementation of public consultations have been raised by the REFIT Platform in an own-initiative opinion in 2017.[8] Points raised included: the extension of the minimum period for feedback from consultations; and greater consultations on draft delegated and implementing acts. It is also urgent to address the main gap – draft IAs continue to be excluded from the Commission's notice-and-comment procedure. However, a recent ECJ ruling established a precedent, making this an important step in the general process of strengthening transparency.

It is promising that the Commission has committed to take those inputs in due consideration and address the identified shortcomings.

On top of the challenges reported in the mentioned 2017 opinion by the REFIT Platform, the ERF would like to draw attention to the following critical elements:[9]

- **Access** – stakeholders and the public continue to experience barriers to meaningful input the decision-making processes, notably when it comes to implementation measures. Barriers include inadequate public notice of consultation opportunities, and web-based commenting procedures that limit the type, length and detail of comments;

- **Representation and expertise** – the relevant guidance by the Commission insufficiently differentiates between the procurement and collection of evidence on

8 Cfr. *REFIT Platform Opinion on the submissions XXII.4.a by the DIHK and XXII.4.b by a citizen on Stakeholder consultation mechanisms*, at https://ec.europa.eu/info/sites/info/files/xxii4ab_on_stakeholder_consultation_mechanisms.pdf.

9 A more elaborated assessment by the ERF of current consultation practices and related ERF recommendations are included in previous contributions by the ERF to EU public consultations, including ERF Communication 15 on the *"European Commission Public Consultation on the Commission Guidelines for Stakeholder Consultation"* (September 2014); and ERF Communication 18 on the *"European Parliament Public Consultation on General Rules for an Open Independent and Efficient European Administration"* (March 2018), at http://www.riskforum.eu/uploads/2/5/7/1/25710097/erf_-_com_15_-_ec_consultation_consultation_14_.pdf and http://www.riskforum.eu/uploads/2/5/7/1/25710097/erf_-_com_18_-_ep_consultation_lap_18.pdf, respectively.

the one hand, and public consultation on the other hand. The two processes are not equivalent: they serve different purposes and rest on different rationales and approaches;

- **'Public docket'** – EU decision-making does not rest on formal public repositories, where all of the information relied upon by decision-makers is collected and is available for public review; and

- **Feedback and justification** – the requirement for decision-makers to explain the legal and factual bases of their decisions, including responding to comments made by the public, is not applied consistently.

3.2.3. Reforms

Key ERF recommendations:

- **Introduce mandatory, legally binding due process standards regulating public consultation** – such standards should cover notice-and-comment procedures and public participation requirements. They should encompass the obligation to establish a technical and factual public record upon which the public has an opportunity to comment and on which decision-makers have to rely. The standards should be part of the provisions of a EU Law of Administrative Procedure;

- **Systematically include all major implementing decisions by the Commission and the EU agencies under the scope of the Commission's minimum standards for consultation** – implementation decisions subject to consultation should include substantive technical or scientific guidelines drawn up by the Commission or the EU agencies; case-by-case decisions which embed risk management assumptions; and all implementing and delegated acts for which an IA is carried out;

- **Require all draft IAs to be published and subject to public consultation prior to the development of a final proposal, adhering to the Commission's minimum standards for stakeholder consultation** – special emphasis should be placed on ensuring that officials account publicly and specifically for the use of inputs received through the consultation process, including explaining why criticisms and recommendations provided by stakeholders have been rejected;

- **Strengthen the distinction between the gathering of evidence and the consultation process, especially for risk management measures, and formally recognise that they are not equivalent** – within the Better Regulation guidelines it is recognised that consultation cannot be a substitute for rigorous gathering of evidence. The comments need, however, to be generally strengthened and to recognise the particular requirements of risk management measures. In the case of measures designed to manage risks, evidence to support state intervention should always be based on a scientific risk assessment process that meets globally-accepted standards. Opinions obtained from consultation processes should not be considered as the equivalent of the outcomes of a formal risk assessment process. This should be emphasised; and

- **Limit the dependence on (online) closed question, multiple choice questionnaires** – this method of gathering information is primarily designed to identify attitudes and behaviours, and works best when dealing with well-established issues, when questions provide for a full range of answers, when respondents are selected on a representative basis, and when the structure of the questionnaire does not 'lead' respondents towards particular outcomes. These criteria are unlikely to be met when officials undertake consultation exercises. A further problem is that, through their design, they exclude qualitative insights – one of the most important contributions of a well-designed consultation exercise. Finally, they may encourage a tendency to focus on the quantity rather than the quality of responses. Consultation should not be seen as a form of participative democracy, using questionnaires as a way of assessing the representativeness of support, or opposition, for proposed measures. Online consultations should not replace the organisation of public hearings with adequate representation of stakeholders and experts.

3.3. Ex Post Evaluation

3.3.1. Background

The Better Regulation package of 2015 has significantly enhanced the organisation and processes to evaluate the relevance, effectiveness and impact of legislative and regulatory interventions. The ERF shares the overall positive appraisal contained in the recent report

by the European Court of Auditors.[10] Under this Commission, the ex post evaluation system has received greater attention and focus of reform than ever in the past, thereby filling a gap evident in previous Better Regulation strategies.

Recent landmark developments include:

- **Evaluate First Principle** – although first introduced in 2010, this principle has been applied with far greater consistency over the past five years, reflecting the commitment by the Juncker Commission to ensure that the EU acquis is fit for purpose and new interventions at the EU level bring actual added value;

- **Publicity and consultation** – the evaluation system is predictable. Planned evaluations are included in the annual work plan of the Commission. They are anticipated by roadmaps, which are subject to a 4-week "feedback consultation". A consultation strategy must be published for all evaluations and includes a mandatory 12-week public consultation covering the main elements of the evaluation;

- **Dedicated, multi-stakeholder governance** – the establishment of the 'REFIT Platform' consisting of a Stakeholders Group and a Member States Group seeks to leverage multi-actor representativeness and expertise. As a result of the 'Lighten the load' web-portal, the REFIT Platform reflects a deliberate attempt to combine various regulatory tools to enhance participation, effectiveness and legitimacy of (simplification) initiatives; and

- **Formalisation, scrutiny and reporting** – the results of all evaluations and fitness checks (and no longer only of IAs) are now reported in Staff Working Documents (SWDs). This formalisation signals, at least theoretically, the full ownership of the evaluation findings and the related recommendations by the relevant Commission service and makes the evaluation report subject to Inter-Service Consultation. The extension of the mandate of the Regulatory Scrutiny Board (RSB) to also review evaluations (albeit selectively) is an additional positive element: the inclusion of the RSB's opinion in the final evaluation report increases accountability. The obligation to regularly report on the performance of the ex post evaluation system and track

10 Cfr. European Court of Auditors (2018), *Ex-post review of EU legislation: A well-established system, but incomplete*, at https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=46063.

progress with the simplification targets (the REFIT Scoreboard) is a further important element.

3.3.2. Areas for Improvement

The system set up by the Commission is comprehensive and ambitious. If not crafted carefully and implemented strategically, risks being unable to reap the full potential from post-implementation reviews. A number of issues remain open:

- **Systematic approach** – by launching the REFIT Programme in 2012, the Commission has sought to review the entire acquis – a radical shift in paradigm compared to the previous typical approach to ex post evaluations. These have typically been confined to single initiatives and individual pieces of legislation. The combination of various evaluation types and methods (e.g. Fitness Checks; Cumulative Cost Assessments; evaluations) resting on slightly different procedural arrangements and led by different Commission services might not contribute to streamlining practices. The plurality of evaluation tools deployed has moreover been aggravated by the recourse to very different methodologies, analytical assumptions and standard statistical values from one evaluation exercise to the other;

- **Scope and overall purpose** – more fundamentally, there still appears to be some ambiguity as to the declared scope of the analyses (and hence their ultimate goal) and the overall purpose of the REFIT Programme. The Commission's Communication establishing the REFIT Platform illustrates well the multiple purposes attached to it. It first places the Platform firmly in the de-regulatory discourse (to identify possibilities for regulatory burden reduction), to then calling on the Platform to discuss wider themes related to sectoral legislation or cross-cutting issues, such as barriers to digitisation or to innovation. Eventually, the Platform may be involved on various reform fronts as an advisory body to the Commission on any matter relating to its better regulation work and the REFIT Programme[11]; and

- **Lesson-drawing for systemic improvement** – tying up the ex post and the ex-ante ends of the policy cycle is challenging. The REFIT Platform arrangements might

11 Cfr. European Commission (2015), *The REFIT Platform. Structure and Functioning,* C(2015) 3260 final.

exacerbate this difficulty because of the potentially increased disconnection between the stakeholders' and public suggestions and evaluation outputs on the one hand, and the inputs needed for new strategic policy elaboration on the other hand. Both the recourse to the 'Lighten the Load' and 'Have your say!' inputs, and the direct involvement of Platform members, in the elaboration of the evaluations (or at least the formulation of the simplification proposals) may drift the evaluation agenda towards relatively shorter term, immediate concerns. This might not necessarily correspond to or be instrumental for achieving longer term policy objectives, unless 'horizontal' lessons are drawn from the various policy approaches and legislative interventions taken in the past and ways to increase coherent design; understand and avoid unintended consequences and 'risk-risk' trade-offs, and better grasp socio-economic impacts as a whole are identified. The findings from the various evaluation exercises are not systematically shared in commonly accessible databases. Learning from good and innovative practices is thus undermined. The systemic benefits from the ex post evaluation function, therefore, are still to be reaped in this respect.

3.3.3. Reforms

Key ERF recommendations:

- **Establish a greater range of strong 'evaluation triggers', including a requirement for the inclusion of a binding review clauses whenever risk management decisions are justified by the use of the Precautionary Principle** - the "Evaluate First Principle" is a powerful self-disciplinary tool and deserves full implementation. The possibility for the Secretariat General to 'prompt' evaluations should be formalised, upon consultation with the Regulatory Scrutiny Board. Whenever a regulatory initiative is taken based on an invocation of the Precautionary Principle, a binding review clause should be mandatorily inserted in the act. If a legislative initiative is adopted without an IA, the resulting regulation must be the subject of a retrospective analysis within a two- to five-year period from implementation;

- **Broaden the scope of evaluations, practices and methodologies to encompass all major implementation decisions** – this would recognise the pivotal role played by these decisions, most notably for policies and legislation designed to manage risks. This implies reviewing substantive guidance issued by EU agencies; major decisions by

EU agencies that embed risk management assumptions; comitology (or equivalent) decisions that affect multiple products, substances or processes; and comitology (or equivalent) decisions subject to regular and detailed scrutiny by the European Parliament. Each retrospective evaluation should place adequate weight to the impacts of EU regulation upon innovation, upon main trading partners and appropriate related guidance should be issued;

- **Clarify the type of evaluation, so that the purpose of the exercise is transparent and guides activity** – evaluations should systematically reflect the holistic approach outlined in the Guidelines, which include by default all five main 'evaluation criteria' (relevance, effectiveness, efficiency, coherence and EU added value) unless due justification is provided for omitting one or more of them. In so doing, the purpose of the evaluation exercise should be a key element in the initial choice as to whether to include any given regulation in the review programme or not, rather than the availability of resources;

- **Establish quality standards for the evidence to be used to support evaluation exercises within the Commission** – recourse to "the best available evidence" should be set as a general, compulsory rule for any kind of evaluation. The Secretariat General should establish, and the Regulatory Scrutiny Board should enforce, quality standards related to the evaluation function in the Commission. For example, these should require scientific studies, information, and data to be based on widely-accepted, standards based on the scientific method. Such standards should be uniform for all type of data collection, validation and use by the Commission, including for IA;

- **Harmonise standard values, methodologies, and approaches used across sectors and over time** – in order to ensure full objectivity, relevance and compatibility of evaluations over time and across sectors, the consistent and systematic use of standard statistical values and assumptions across individual evaluation exercises must be ensured. The Secretariat General should consolidate current practices and approaches in close coordination with the policy DGs and the JRC, and formalise them in the future revised Guidelines;

- **Enhance data collection and monitoring coordination for implementation and compliance with EU legal and regulatory decisions** – the Commission, jointly

with the Member States, should consider upgrading existing monitoring mechanisms for implementation of and compliance with EU policy and regulatory decisions, including using multi-stakeholder public-private platforms; relying on networks of authorities; and organising 'composite meetings' throughout the life-cycle of the measures;

- **Up-grade the capacity of the ex post evaluation system to draw 'horizontal' policy lessons from individual evaluations ('horizontal' added-value)** – the Secretariat General should improve the inter-operability and the use by the Commission services of all relevant databases hosting findings and data related to and resulting from individual evaluation exercises. This is the precondition for a systematic consolidation in dedicated analyses of cross-sectoral impacts and unintended consequences. For risk management measures, negative, horizontal impacts are likely to include risk-risk, defensive R&D, demand stigmatisation, loss of existing technologies, increases in time, cost, and uncertainty of innovation projects, and delocalisation of innovation and R&D; and

- **Utilise the findings of ex post evaluations to support the sharing of best practices amongst EU agencies** – this should strengthen existing informal initiatives.

3.4. Regulatory Oversight

3.4.1. Background

The transformation of the Impact Assessment Board (IAB) into the Regulatory Scrutiny Board (RSB) is one of the flagship reforms of this Commission. The change implies several fundamental and positive advances:

- **Mandate** – reporting directly to the First Vice-President in charge of the Better Regulation portfolio, the RSB now oversees the appropriateness and quality of draft IAs as well as selected evaluations. The extension of its mandate sets the basis for a more uniform level of scrutiny and the enforcement of common quality standards on the ex-ante and ex post ends of the Commission analytical function. With regard to IAs, the RSB considers the overall draft document (from the accuracy of the problem definition, the logic of intervention, the appropriateness of the options and the types

of data, assumptions and methodologies used) – and not just the correctness of cost calculations, as is the case for regulatory oversight bodies in several EU Member States;

- ***Membership*** – the composition of the RSB has been broadened to include up to seven members, of which three are experts from outside the Commission civil service. Not only has the number of members increased compared to the IAB, but also the workload has been rationalised since the members now operate on a full-time basis and they have a (relatively small) secretariat; and

- **Independence** – the presence of external experts in the RSB increases the de facto independence from the Commission services submitting their draft IAs.

Considering the mandate and the resources available, the RSB has significantly contributed to enhancing the quality of the analyses carried out by Commission services.

3.4.2. Areas for Improvement

- **'Gate-keeping' function** – the RSB intervenes relatively early in the Commission internal decision-making process. While this allows for an early exchange with the proponent service on the adequacy of the draft IA, the RSB is then excluded from subsequent revisions of the IA further to the Inter-Service Consultation. The lack of 'power of return', which would entitle the RSB to formally prevent a proposal from being table for discussion by the College is arguably determined by the legal architecture (collegiality) of the Commission. It is only partly compensated by the external accountability triggered by the obligation for the Commission to publish the RSB opinion once the proposal is adopted. The RSB powers have remained comparatively soft and based on the internal credibility of its work, and not seldom can its recommendations still be relatively easily by-passed;

- **Scientific oversight** – a key shortcoming of the current system is the de facto absence of a formalised scientific oversight body. In 2015, the position of the Chief Scientific Advisor was not renewed, and the Scientific Advice Mechanism (SAM) has been established instead. Despite a relatively broad mandate, the Group of Scientific Advisors has so far not taken over leadership in establishing a new, coherent policy

for the collection and use of scientific advice; and in enforcing agreed standards for scientific excellence and impartiality; and

- **Communication** – one of the core functions of many regulatory oversight bodies in OECD countries is also to formally communicate regulatory policy to the public both domestically and in international fora, and (sometimes also informally) advising and prompting regulatory quality improvements across regulatory agencies. The RSB issues annual reports and has hosted high-level conferences. While these are most relevant and welcomed initiatives, because of its mandate and allegedly lack of resources, the RSB has not been able to profile itself as the key champion for Better Regulation that it should be.

3.4.3. Reforms

Key ERF recommendations:

- **Widen the scope of the Regulatory Scrutiny Board to include the implementation of risk management decisions by legal, administrative and other mechanisms** – this should ensure that the RSB oversees the interventions of the EU's Administrative State;

- **Expand the mandate of the Regulatory Scrutiny Board to encompass oversight of the quality of scientific evidence used to justify interventions** – to this end, organisational and procedural arrangements should be designed to ensure the closest coordination possible between the Regulatory Scrutiny Board and the Group of Scientific Advisors; and

- **Require opinions of the Regulatory Scrutiny Board to be published as soon as they are adopted** – this will improve transparency and accountability.

4. Improvement Themes

- This section focuses on six cross-cutting themes:
- Objectives of Better Regulation (Section 4.1.);
- Management of Risk (Section 4.2.);
- Science and Evidence – General (Section 4.3.);
- Science and Evidence – Access to Expertise (Section 4.4.);
- Dynamic Impacts of Regulation (Section 4.5.); and
- Implementation of Risk Management Laws and the Administrative State (Section 4.6.)

4.1. Objectives of Better Regulation

4.1.1. Background

Better Regulation strategies are used widely throughout the OECD area to enable governments to deliver the social and economic goals of law-making without regulatory failure, whilst, at the same time, ensuring that modern standards of governance are met. They seek to establish decision- making processes, based on the best available evidence, that meet the needs and expectations of citizens, including businesses, in the most legitimate, proportionate and cost-effective manner. They recognise and limit unintended consequences. They strengthen legitimacy. And, the best of them prioritise important regulatory goals, most notably the protection of fundamental rights, the promotion of a high standard of health and environmental protection, the creation of a dynamic market economy, and the stimulation of incentives to invest in risk-taking and innovation.

In 2015, the European Commission set out its goals and objectives for the new Better Regulation agenda. Interventions must be well designed and based on evidence. They should help unlock investments for growth and make life easier for citizens and businesses. Specific objectives set out in the Communication include better and wider consultation, including review of measures that implement laws; better justification of interventions; improved regulatory process management; stronger oversight; and reduction in regulatory burden. Non-binding guidelines provide clarification. These require interventions to minimise costs, to mainstream sustainable development and to be based on processes that are open, transparent, and informed by the best available evidence and the results of stakeholder consultation.

Last year, the Commission reviewed the progress had been made to implement the new approach. It issued, as part of its evaluation, an up-dated Communication setting out new political commitments. These require the Better Regulation Agenda to ensure that interventions respect proportionality and subsidiarity, increase legitimacy, reduce regulatory burden, and strengthen enforcement of EU law.

4.1.2. Areas for Improvement

There appear to be inconsistencies between the two Communications, and hence potentially in the political objectives of the Commission's Better Regulation Agenda. Moreover, the 2017 Communication fails to include commitments, set out in 2015, to base interventions on evidence and to use regulation to promote innovation.

A further weakness in the Commission's strategy for promoting Better Regulation is the lack of coherence between political commitments, set out in the two Communications, and the non-binding principles used to shape the behaviours of officials when designing and implementing laws. There are also weaknesses and gaps in these principles. They do not, for example, require interventions to demonstrate that benefits justify costs, or to ensure that interventions strengthen the dynamism of markets, productivity, and incentives to innovate.

Finally, the overall design of the strategy reflects traditional understandings of law-making at EU- level, rather than recognising the increasing importance of centralised implementation of complex laws through an 'Administrative State'. (This is explained in more detail in Section 4.6.)

4.1.3. Reforms

Key ERF recommendations:

- **Develop a new set of political commitments and objectives for the Better Regulation Agenda that strengthen commitments to base decisions on evidence and to use regulation to promote innovation** – the commitments set out in 2015 and those developed in 2017 should be structured and consolidated around the internationally established core principles for good regulation and include, as a minimum, the principles of necessity, effectiveness, proportionality, predictability, transparency, accountability, simplicity and participation. The commitments of the Commission should be made explicit and consistent in the Better Regulation Communication as well as in the underpinning Guidelines and Toolbox;

- **Include in a revised Better Regulation Communication, a specific political commitment to use the regulatory process to promote investment in innovation** – this should recognise the requirement set out in Council Conclusions and in the Treaty and explicitly recognise the importance of the Innovation Principle;

- **Make the Better Regulation Guidelines a formal political commitment** – these, in effect, influence the behaviours of officials and structure the development of technical guidance, so-called 'toolkits'. They should, therefore, receive greater prominence and form part of the political commitments made by the Commission. Their use should be made mandatory;

- **Revise the Better Regulation Guidelines to require all interventions to demonstrate that benefits justify costs and that the least restrictive means of achieving the regulatory goal has been employed** – these requirements should replace the current "minimum cost" test;

- **Strengthen the requirement, set out in the Better Regulation Guidelines, to base interventions on the best available evidence, by requiring adherence to explicit quality standards and by including it in the Better Regulation Communication** – this should increase public confidence in the quality of decision-making; and

- **Expand the Better Regulation Communication and Guidelines to require officials to ensure that new and existing interventions are proportionate and coherent with other parts of the regulatory framework** – this should seek to avoid design flaws whereby, for example, poorly-designed or conflicting risk management laws create obstacles to investment in innovation.

4.2. Management of Risk

4.2.1. Background

Public risk management is one of the fundamental ways in which governments solve problems and meet the expectations of citizens. Today, it is most readily associated with government actions to protect people at work and to protect citizens and the environment from harm. But as a core function of government, risk management has been a potent and pervasive form of public policy for more than 200 years. In that period, it has been used to support a range of varied policy objectives, most notably creating the conditions for economic prosperity by managing risks to trade and investment; protecting industrial workers from the impacts of economic activity; and protecting citizens and the environment from ruinous risks.

Public risk management can be broadly defined as any government action designed to prevent, reduce, or re-allocate risk. It includes actions to manage risks posed by technologies, economic activity, and lifestyle choices.

The EU's institutions, along with governments in most other modern economies, have progressively expanded their risk management responsibilities. These now encompass issues such as product safety, food safety, pharmaceuticals, chemicals, environmental protection, public health, occupational health and safety, and consumer protection.

The Toolkits contained within the Commission's 2015 Better Regulation integrated approach agenda recognise this. Risk management is identified as a separate and important policy domain. Critical information is provided for officials most notably definitions of 'hazard' and 'risk'. It is implied that scientific evidence should be used to identify risks, and the importance of considering complex trade-offs between benefits and risks is highlighted. Guidelines identify the possibility that actions taken to manage a target risk may, through

a process of unintended consequences, trigger or amplify other risks – the so-called risk-risk paradigm. Finally, the guidance makes it clear that it is undesirable for officials to seek zero risk through laws or their implementation. All of these aspects of the guidance are to be welcomed.

4.2.2. Areas for Improvement

Despite these improvements, the new guidelines provide only limited advice about how to make the most effective use of IA tools, when seeking to manage potential risks posed by technology or lifestyle choices. Within the guidelines more emphasis needs to be placed on the distinctive nature and importance of this 'horizontal' theme of EU-level policy-making.

Moreover, the guidelines create the impression that risk management measures are mostly based on applying the Precautionary Principle. This is inconsistent with the Commission's Communication on the Precautionary Principle that specifies the limited, and unusual, circumstances when it may be used to legitimate risk management actions.

4.2.3. Reforms

Key ERF recommendations:

- **Develop and adopt common principles and minimum detailed standards for risk analysis** – this could be achieved through, for example, the adoption of a new Communication. It should develop the ideas and concepts set out in the EU General Food Law; distinguish between risk assessments used for determining policy and designing legislation, where scientific evidence should inform decision-making, and the processes of implementing laws where, unless required otherwise by legislation, decisions should be based on scientific evidence; and, require all risk assessments to be informed fully by real world experience and evidence, and to be based on normal handling and usage, rather than solely on hypothetical exposures or synthetic laboratory conditions;

- **Expand the guidelines for impact assessment and risk management to recognise that the intervention logic for ex ante assessment of measures designed to manage risks posed to human health, public safety, and the environment should be based on the findings of a formal science-based risk**

assessment – this should meet the requirements for best available science and risk analysis set out in other Commission-wide policies. It should provide a justification for government intervention that distinguishes evidence of hazard from assessment of risk. It should be based on credible real world experience and normal handling and use. As well as identifying the benefits of government action, it should provide, through a science-based analysis of cause-and-effect, a framework for the design of appropriate and effective risk management options;

- **Base interventions on a proportionate assessment of the risk of exposure, rather than the hazard of intrinsic properties** – this should ensure that the costs and benefits of interventions can be properly assessed. It should help avoid negative, unintended consequences, such as risk-risk outcomes or reduced incentives to innovate or to allocate capital to Europe. Analysis of exposures should focus on normal handling and use, rather hypothetical exposures or theoretical laboratory-based studies;

- **Require measures designed to protect human life, public safety, or the environment to re-assess the original scientific evidence and risk assessment used to justify intervention, as well as examining new scientific evidence, within an appropriate time horizon** – reviews should encompass legislative and implementing measures and should be carried out in accordance with Commission-wide policies for the quality of scientific evidence, and risk analysis;

- **Revise the guidance to emphasise that risk management decisions based on the Precautionary Principle are limited to certain, specific circumstances where data is missing** – this will ensure coherence between the Commission's Communication on the PP and the Better Regulation agenda. Use of the Precautionary Principle is restricted to highly unusual circumstances defined by certain types of uncertainty, including specific gaps in understanding. Once these doubts or gaps in knowledge are resolved, it should no longer be necessary to apply the Precautionary Principle;

- **Highlight the need to ensure that all policy interventions designed to manage risks include a clear statement of measurable final outcomes, intermediate behavioural changes, and actions by affected parties** – this will ensure that interventions deliver measurable improvements in mortality and morbidity,

for example, that are clearly linked to the intervention logic that provides the rationale for government action;

- **Recognise explicitly that knowledge, derived from the scientific method and meeting internationally-accepted standards of quality, should be the pre-eminent form of evidence used for managing risks** – most of this evidence will come from natural science and engineering, because of the nature of the risks to human health and the environment managed by the EU institutions;

- **Require scientific studies that are used to justify regulatory interventions to be available for public review, to meet the standards of the scientific method, to subject to transparent peer review, and to have validated protocols, that make the tests capable of being replicated by other researchers** – this should ensure greater confidence in the scientific evidence used to provide the rationale for the use of the powers of the state; and

- **Expand the guidelines to include a series of specific additional requirements to be met when using impact assessment tools to assess potential risk management interventions** – these are shown below:

  Problem Definition

  - Recognise the characteristics of different types of threats (including lifestyle and technological risks), define them on the basis of scientific knowledge, and take account of this in assessing problems, identifying risk management options, and assessing the costs and benefits of policy action;

  - Base all scientific risk assessments on the best available scientific and technical information, and ensure that conclusions about a problem's potential risks to human health, public safety, and the environment assessments take full account of the weight of scientific evidence. Assessments should, moreover, distinguish clearly between 'hazard' and 'risk', identify realistic exposures to hazards; and highlight scientific uncertainties (using well-established typologies of different types of uncertainty); and

- Require risk assessments to be subject to peer review if they are to be used to support major legislative or regulatory decisions.

Objectives

- Require objectives for new or revised EU-level risk management rules to recognise the importance of risk-taking for innovation, economic prosperity and long-term improvements in the quality of life; and

- Base objectives on quantified improvements in health or the environment, requiring officials to demonstrate a clear and credible link between problem, action, and result.

Assessment of Impacts

- Require officials to make extensive use of quantitative analyses when assessing the costs and benefits of different risk management options. These should include, wherever appropriate, monetary analyses and the use of modern cost effectiveness analyses. Assessments of potential benefits and costs should, moreover, recognise potential unintended negative consequences, and the loss of existing benefits, of specific policy options.

Comparison of Options

- Recognise that risk management decisions can, under certain circumstances, create negative unintended consequences, and require risk managers to take this into account when assessing options (the 'risk-risk' problem); and

- Examine the 'workability', 'effectiveness' and 'legitimacy' of new risk management tools and mechanisms, including substance-based substitution, precaution, and direct restrictions on lifestyle activities. The IA guidelines should include, for instance, a comprehensive description of the problems associated with using hazard-based strategies to manage risks.

4.3. Science and Evidence – General

4.3.1. Background

When making decisions about the best way to manage risks to citizens and the environment, scientific evidence provides unique insights. Unlike opinions or values, it enables governments to identify the existence of hazards and their causes; to determine which hazards pose the greatest risks; to reduce uncertainties; to characterise risks; and because it is often able to identify the potential benefits of action, to allocate resources rationally.

Over the last two decades, significant improvements have been made in the way in which the EU's institutions collect and use scientific evidence to assess and manage the risks to humans and the environment posed by technologies and lifestyle choices. In some policy areas, this has stimulated the development of policies and processes that deliver widely-respected high quality scientific assessments on a regular basis. However, the process of reform remains incomplete. The EU's institutions lack powerful horizontal institutions, policies, and guidance designed to ensure that scientific evidence and advice is of the highest quality; that processes of scientific assessment are consistent; and, that standards of good administration are met.

Many of the scientific assessments carried out by the EU institutions are of high quality, and a number of good practices have been developed to improve consistency and utility, as well as to share ideas across different parts of the Commission. However, there remains a clear, general lack of consistency, transparency, and predictability. In too many cases, scientific assessments do not meet world-leading standards.

The challenge facing the European Union is to recognise these weaknesses and to undertake the necessary reforms to improve and strengthen scientific assessments. It is the natural complement to the OECD's regulatory principles that all member governments, including the European Commission, support. It is the next step for the Commission's much-admired Better Regulation strategy. It is the means to deliver high standards of protection for Europe's citizens and for the environment, whilst at the same time helping to stimulate risk-takers to invest in the innovations needed to stimulate growth, prosperity, and sustainability.

Whilst the importance of scientific evidence is not recognised explicitly, general principles for the using evidence to support decision-making are included in the toolkits that form part of the Better

Regulation integrated approach. They focus on the need for evidence to be of high quality, transparent, credible, proportionate, and based on reality. These principles, along with useful examples provided in the guidance, are to be welcomed.

4.3.2. Areas for Improvement

It is, however, a major gap in the scope of the Better Regulation agenda that scientific evidence is not considered directly and separately. It is the pre-eminent knowledge input for identifying and managing risks; one of the most important policy domains that falls within the scope of the EU's powers. Evidence drawn from the scientific method also informs policy development in a wide range of other areas of activity.

4.3.3. Reforms

Key ERF recommendations:

- **Rest political responsibility for the quality and effectiveness of the overall process of collecting and using scientific evidence to make risk management decisions with the First Vice-President in charge of Better Regulation** – this portfolio, which aims to improve the quality of regulatory decision-making, is a logical complement to the existing Better Regulation policy, and should be closely co-ordinated with the Commissioner for Research, Science and Innovation, and with the Commissioner responsible for the Joint Research Centre;

- **Establish formal central oversight with responsibility for ensuring the effective functioning of the entire scientific advisory system** – among its responsibilities, scientific oversight should include defining and enforcing the quality, objectivity, utility, and integrity of scientific evidence and advice used to guide and inform decision-making in all parts of the EU's executive government, including agencies. Adequate resources, staff and expertise should be allocated to this function to ensure compliance, by all directorates and agencies, with common policies and guidelines.

Scientific oversight must, moreover, be independent of the Joint Research Centre, EU agencies, and policy DGs;

- **Develop and adopt, for example in a new European Commission Decision, minimum standards for the quality, collection, validation, and use of scientific evidence that all directorates and agencies must respect** – the Decision should:

  - Require all forms of regulatory decision-making to be guided by the best available science gathered using widely accepted, consistent, open and transparent processes, in order to arrive at a well-founded scientific assessment, carried out by the best eminent and relevant experts, based on the weight of evidence;

  - Set out robust quality controls for ensuring that scientific evidence meets this standard, including a catalogue of characteristics of the best available science; requirement to use the established methodology of Systematic Evidence Review to collect and assess evidence; use of peer review, and provision of an independent right of appeal, prior to dissemination of the findings of significant scientific assessment;

  - Recognise the threat to scientific integrity posed by the growth of low quality studies, most of which cannot be validated or reproduced and hence do not meet the standards of the scientific method, and establish specific, additional requirements for 'outlying' studies to be assessed independently, using, for example, clear test protocols to filter out laboratory contamination; and

  - Establish 'excellence', regardless of funding, and relevance as the only criteria for determining whether or not scientific evidence is included within a scientific assessment.

- **Revise standards and processes for public consultation to recognise the difference between opinions collected through such processes and the outcomes of scientific assessments** – they should recognise explicitly that public consultation is not a substitute for collecting scientific evidence through formal processes of scientific assessment. (Science is not opinion, and, unlike public consultation, does not rest on the paradigm of representativeness.);

- **Develop supplementary guidelines that clarify the application of the Precautionary Principle in regulatory decision-making** – these should be in addition to and should not replace the existing Commission Communication. They should re-state the requirements of the Communication, emphasising that the Precautionary Principle should only be used, in a limited range of circumstances, as a justification for risk management measures, and that it should not be used to influence scientific assessments that form part of the processes of understanding risks. All agencies and directorates should be reminded of these requirements; and

- **Require the Regulatory Scrutiny Board (RSB) to ensure that all sections of ex ante IAs fully meet the relevant requirements set out in the Better Regulation guidelines** – the RSB should also review, using support from JRC experts, the scientific evidence used to support Commission initiatives designed to protect human health, public safety, or the environment.

4.4. Science and Evidence – Access to Expertise

4.4.1. Background

Identification, assessment and management of risks to humans and the environment posed by technology and lifestyle is one of the principal roles of modern government. Citizens expect high standards of protection, whilst continuing to enjoy the benefits of investments in science and technology. To achieve this demanding trade-off, most governments rely upon evidence derived from scientific assessments undertaken by experts. Through these well-established processes, decisions can be made that recognise risk, that demonstrate the benefits of state intervention, and that deliver successful regulatory outcomes.

Expert scientific assessments, used to guide risk management decisions, must meet two criteria, if they are to support the actions of governments. On the one hand, they must provide the best available advice. If this standard is not met, then there is a risk of regulatory failure whereby state intervention creates additional risks (risk-risk trade-offs) or significant unintended costs. Set against this, advice should also be impartial. It should be provided in the public interest: private concerns, beliefs, ambitions, or interests should not influence it. If both tests are met, then advice, provided by scientific assessments, will retain its integrity, underpinning the legitimacy of regulatory decisions based on it. (It is not in the

public interest to assume that all scientists who receive funding from the private sector lack scientific integrity or the capacity to act impartially.)

All too often, officials responsible for obtaining scientific advice deem these twin requirements to be satisfied if evidence, and related advice from scientific assessments, is supplied solely by scientists from academia, and ideally without any significant funding or other links to the private sector. Such an approach is, increasingly, no longer feasible or desirable. It is based on a series of out-dated assumptions about who undertakes and funds R&D investment; the types of risk society seeks to manage; and, the nature and causes of bias.

Knowledge generation has become a more complex process, in part reflecting government policy. R&D is, today, undertaken primarily by the private sector itself or through public-private relationships with academics. Over 85% of all R&D expenditure involves industry directly or indirectly, and safety research, much of it in response to mandatory requirements, is almost entirely funded by the private sector. At the same time, the focus of risk management has shifted from managing large, well-established hazards posed by the production of technologies, to controlling, smaller, more complex and heterogeneous threats to users of technologies. Effective risk management now involves a greater understanding of the application of technologies, an area of knowledge pioneered by industry.

Our understanding of bias, and its nature and causes, has advanced too. When scientific experts provide advice to policy-makers and regulators, bias occurs whenever secondary or private interests unduly influence judgements. This reflects conflicts-of-interest that inhibit the capacity of the expert to advise impartially and in the public interest. Arguing that bias may undermine the quality of advice and create a perceived lack of impartiality, governments have sought to avoid it by identifying, through a process of disclosure, evident financial conflicts of interest and, thus, excluding certain experts, principally those linked to the private sector. This is the approach used by most of parts of the European Commission: it is no longer appropriate. Existing good practice along with recent findings from behavioural psychology, suggests that this approach, with its primary emphasis on material reward factors, is out-of-date and incomplete.

Instead, today's research suggests that personal biases, even for those acting in the public interest, reflect an extensive range of complex conflicts of interest. Some are conscious whilst others are not. They include financial, academic-professional ambitions, power, status, beliefs and ideologies, political affiliations, national cultures, and knowledge (or lack of it). It is now considered more accurate to consider bias as part of the human condition because it provides a mechanism whereby information can be processed in a complex world. We all have it. Thus the problem facing officials is not how to avoid bias, rather how to manage it.

In the light of this, and recognising changes in the way in which knowledge is generated and disseminated, new approaches are needed for the selection of scientific experts for scientific committees or panels that support policy, legislative, or regulatory decision-making by governments. Unless this is done, then the European Commission faces the likely progressive loss of access to some of the best science and best scientific experts, eroding the quality of scientific assessments, and making regulatory failure more likely.

4.4.2. Areas for Improvement

The European Commission's Better Regulation agenda does not address bias, and the conflict-of- interest that cause it, as a cross-cutting, 'horizontal' issue. This is a significant gap in the coverage of the policy. It is fundamental assumption of evidence-based decision-making policies pursued by modern governments, that the most eminent and relevant experts undertake scientific assessments, the principal knowledge generation process supporting risk management decisions. Current policies, pursued on a piecemeal basis by individual agencies and other parts of the Commission and focused primarily on financial issues, are unlikely to achieve this in a systematic way.

4.4.3. Reforms

Key ERF Recommendations:

- **Set out the key principles for the selection of scientific experts and for the operation of scientific committees in, for instance, a new Commission Decision** – these should be minimum standards and should apply to all forms of scientific committees in all agencies and directorates. The Decision should:

- Require scientific assessments to be carried out by the best available experts who meet accepted, transparent standards of eminence, expertise, and relevance;

- Allow all relevant scientists who meet these agreed standards of eminence, expertise, and relevance to be eligible for selection;

- Establish rigorous, fair, and transparent 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 expert group, committee, or panel. This should include, but should not be limited to: beliefs, ideals, ideologies, political affiliations, support for 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 benefit or substantial evidence of personal beliefs or commitments or ideological perspectives that suggest predetermination;

- Strengthen confidence in the integrity of the process of scientific assessment by ensuring that committees or panels are institutionally independent and separate from ideological and political influence;

- 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;

- Establish standard rules of procedure for scientific committees;

- Limit the scope of mandates to scientific experts to questions that are capable of being answered using scientific experts; and

- Require outcomes of scientific assessments to be subject to independent peer review. All draft assessments should be reviewed procedurally, whilst significant assessments should be subject to an additional substantive review. This will further enhance public confidence in the integrity of the process.

4.5. Dynamic Impacts of Regulation

4.5.1. Background

Modern IA processes recognise that, when making risk management decisions, interventions seek to change behaviours, thereby mitigating or eliminating harms. In turn, behavioural change triggers dynamic impacts that are, by their nature, complex, but go beyond simple costs of complying with new requirements. Dynamic responses to risk management rules can include creating the conditions for risk-taking or creating new risks or eroding incentives to innovate or influencing the allocation of capital or undermining the operating efficiency of businesses or triggering closures and subsequent adjustment costs. A small number of leading countries in the OECD are have begun to take steps to identify these dynamic changes and to ensure that they are taken into account when officials develop new interventions or examine the effectiveness and wider impacts of existing measures.

The European Commission's Better Regulation integrated approach encourages officials to consider some of the potential dynamic impacts of interventions. They recognise the role of productivity, and investments in innovation, in underpinning economic growth. They highlight the importance of creating appropriate framework conditions to encourage competitiveness and thereby stimulate dynamism and productivity growth. Officials are also encouraged to consider potential impacts of regulatory decisions on value chains, investment decisions, global capital allocation, and the territorial heterogeneity of certain sectors.

This modern approach was further reinforced in 2017 when the European Commission issued a revised version of the Better Regulation Guidelines and related Toolboxes. They replaced the equivalent 2015 documents. As a part of this process, technical guidance for assessing the potential impacts of proposed legislative measures on innovation was improved (Research and Innovation Tool #21). In a number of areas, these new guidelines represent a significant step forward. Major improvements include greater recognition of the role of corporate investment in R&D in creating ideas; preference for technologically-neutral interventions; emphasis on consultation with business, so as to understand potential innovation issues; requirements to consider regulatory design, thereby improving coherence and improving certainty; preference for utilisation of technology-neutral and

outcomes-based rules; improved definition of 'Defensive R&D'; and, indirectly, recognition of the Innovation Principle.

All of these improvements are to be welcomed. They provide officials with the beginnings of a comprehensive toolkit with which to consider potential dynamic impacts of risk management interventions.

4.5.2. Areas for Improvement

There are, however, important gaps in the toolkits. There is, for example, only a limited recognition of the impact of risk management rules on process industries. Poorly designed rules undermine operating efficiency or increase capital intensity without enhancing process efficiency. More needs to be done, as well, to strengthen awareness of adjustment costs that are associated with closures, job losses, and other forms of reduced economic activity. Modern research suggests that economies do not always smoothly adjust to change and that job losses impair human capital and can, in certain instances, create adverse health outcomes – the so-called health-health paradigm.

Whilst there is a greater focus on innovation in the guidance, it continues to place too much emphasis on start-ups and radical new ideas. Most innovation takes place in large, existing companies, and frequently involves the continuous improvement of existing process, product, service, and organisational technologies.

The guidelines remain, in many respects, focused on a supply-push model of innovation, whereby governments emphasise improvements in the process of developing and disseminating ideas. Although this is important, it is only one aspect of the 'framework conditions' that stimulate innovation in mature economies. Taken together, these include social attitudes (risk, science, new ideas), access to markets, and access to key inputs of ideas, people, capital, and infrastructure. As a result of failing to consider this wider framework, the guidance does not highlight, for example, the impact of risk regulation on risk aversion, consumer confidence, stigmatisation, and technology choices.

Finally, the guidance fails to consider adequately two further major interactions between risk regulation and innovation. When considering regulatory design, it fails to highlight the impact on innovation of designing risk management measures based on hazard rather

than risk. It also fails to highlight fully the impact of risk regulation on the capitalised cost of development because of regulatory-induced increases in time-to-market, costs and uncertainty.

4.5.3. Reforms

Key ERF recommendations:

- **Revise the 'Competitiveness' guidelines (Sectoral Competitiveness Tool #20) to encourage a greater focus on operating efficiency rather than costs** – this should align the activities of regulators with the approach taken by many companies to business performance. It recognises that the most competitive companies seek to meet world-class levels of cost, quality, variety, and flexibility at the same time. This is an inward-looking capability that goes beyond simply focusing on low cost. By optimising operating efficiency, in combination with optimal asset utilisation, companies contribute towards meeting the specific risk-adjusted cost of capital, set by the global market for capital;

- **Expand the 'Competitiveness' guidelines (Sectoral Competitiveness Tool #20) to require officials to consider a rigorous examination of adjustment costs when examining interventions** – this should ensure that a 'real world' approach is taken to considering the impact of regulatory change. It should, moreover, be considered in two separate stages: job losses or other economic reductions should be considered separately from any estimated compensating changes;

- **Improve the 'Innovation' guidelines (Research and Innovation Tool #21) to highlight the need for officials to consider impacts of innovation on a wider range of framework conditions, including social attitudes, access to markets, and access to key inputs (ideas, people, capital, and infrastructure)** – this should ensure a more complete assessment of the impact of risk regulation on innovation;

- **Expand the 'Innovation' guidelines (Research and Innovation Tool #21) to encompass an explicit recognition of the value and importance of considering the Innovation Principle when designing interventions** – this

should help maintain focus on the importance of stimulating incentives to invest in innovation;

- **Enhance the 'Competitiveness' guidelines (Sectoral Competitiveness Tool #20) by increasing the range of specific regulatory impacts that should be considered by officials by adding capitalised costs of development, technology choices, stigmatisation, use of hazard-based measures, and regulatory coherence** – this builds on evidence, identified by extensive ERF research of the principal cross-cutting negative impacts of risk regulation on innovation; and

- **Strengthen the 'Innovation' guidelines (Research and Innovation Tool #21) by requiring interventions to avoid regulating new technologies specifically and to focus instead on the products they generate that have a specific impact on society** – this should help strengthen incentives to invest in the development of and dissemination of new technologies in the EU.

4.6. Implementation of Risk Management Laws and the Administrative State

4.6.1. Background

Implementation of the EU's risk management laws takes place primarily through the actions of centralised institutions and decision-making mechanisms that form part of an administrative state. Increasingly, it is these implementation processes, and the decisions they generate, that have the greatest negative and positive impact on incentives to innovate and on the achievement of high standards of protection for citizens and the environment.

Over the last twenty years there has been a major increase in direct administration and regulation by the EU's institutions, most notably in policy areas such as competition law, supervision of financial markets and related institutions, internal and external trade, and management of technological risks.

The EU's institutions, along with governments in most other modern economies, have progressively expanded their responsibilities for managing risks. These responsibilities now encompass issues such as general product safety, food safety, pharmaceuticals, chemicals,

consumer goods, environmental protection, public health, occupational health and safety, and consumer protection.

Meeting these policy objectives has significantly expanded the scale and nature of the administrative state at EU-level. At the same time, it has triggered the evolution of new complex decision-making mechanisms, some of which are structurally flawed. These changes have occurred because of the legal and institutional strategies that the EU's institutions have used to manage risks.

At EU-level, moreover, an administrative state has emerged without any formal strategy or plan. Its decision-making mechanisms and institutions are the result of a piecemeal approach, reflecting different and separate policy objectives, and older approaches designed to resolve different problems.

Taken together, these changes have exposed major weaknesses in the governance of the EU's institutions. Citizens and business are faced increasingly with direct action by the EU's institutions without having corresponding legally enforceable procedural rights to challenge them. Existing 'soft law' administrative procedures and requirements of the EU institutions do not, on their own, sufficiently protect the right of citizens and businesses to good administration. And, judicial review by the EC courts has not created a framework of procedural standards to match the growth in the power of the administrative state at EU-level.

4.6.2. Areas of Improvement

Administrative guidelines, setting out process standards for regulatory decision-making, issued by the European Commission as part of the Better Regulation strategy have not resolved fully the weaknesses in the decision-making processes used by the EU to manage risk. There are gaps in the scope of the standards (they do not apply fully to implementing processes, including comitology and its replacements, or to agencies or to substantive guidelines), and in their contents. There are, for example, no consolidated standards for the quality of scientific evidence that can be used to inform risk management decisions.

Action is needed to reform the governance of the EU's administrative state. For this to be achieved, attitudes to law-making must change amongst EU-level opinion-formers and

policy-makers: shared beliefs about the governance of law-making, and about the scope and complexity of their application, continue to be influenced by ideas that no longer reflect current practice. Directives have been replaced by Regulations; and, decentralised implementation has given way to centralised institutions and processes.

Reform of the institutions and mechanisms used by the EU to implement risk management laws offers an opportunity to further develop the Better Regulation strategy.

4.6.3. Reforms

Key ERF recommendations:

- **Work with the European Parliament to develop and adopt a comprehensive Law of Administrative Procedures** – this should embed the principles of good administration into law, provide legally enforceable standards and procedural rights, and encompass all significant rule-making and adjudication processes;

- **Revise the Better Regulation integrated guidelines to strengthen further the focus on Implementing and Delegating Acts (the revised forms of comitology)** – this should ensure that all significant legal implementing measures are subject to an ex ante IA;

- **Require all legal implementing measures that ban or restrict the use of a substance or technology to undergo a comprehensive IA, including the impacts of substitution and substitutes** – this should enable regulators to understand better the costs and benefits of implementing decisions, including potential risk-risk and risk-benefit trade-offs, and dynamic regulatory impacts;

- **Expand the scope of the Better Regulation integrated guidelines to include all substantive guidance developed by the EU's risk assessment agencies** – this is a form of soft law that clarifies the meaning or scope of a law or defines the technical requirements that businesses must meet, if their products or materials are to satisfy standards of safety or efficacy. Because these guidelines impose costs or embed assumptions about the social acceptance of risk or establish ways to manage risks, they are a hidden form of rule- making;

- **Expand the remit of central quality oversight of the Regulatory Scrutiny Board (RSB) to encompass all of the processes used to implement proportionate risk management legislation** – this should ensure that all parts of the policy cycle are properly examined by the RSB; and

- **Require the EU's risk assessment agencies to develop a set of formal best practice standards for the development of substantive guidance, where these have the effect of influencing behaviour of affected parties** – this could be achieved by working with the EU-ANSA network, for example, to encourage the exchange of best practice.

5. Conclusions

In adopting such a comprehensive and ambitious strategy, the Commission has set the tone for a major examination of not only the overall approach to Better Regulation but also the raison d'etre of EU Policy-making. Better Regulation has been established as a critical test of the credibility of the EU institutions, what they stand for and what they ought and can deliver for citizens. How this will inform future EU risk management decisions, in particular, is of paramount relevance.

The Commission's Communications are not, of course, the end of the process of applying Better Regulation ideas to the management of risk or other policy domains. It will evolve as it faces the challenge of implementation over the forthcoming decade. Looking ahead, a number of challenges will need to be overcome, including:

- **The nature of law-making at EU-level is changing** – it is moving away from the development of new secondary legislation implemented by Member States and towards a focus on implementation by direct EU-level institutions using a range of legal and administrative measures. This will involve considerable use of agencies, delegated and implementing acts, technical standards, substantive guidance, and administrative discretion. The Better Regulation strategy will need to reflect this and adapt accordingly. This will require the scope of regulatory process standards and tools to be significantly expanded.

- **Clear criteria and standards for regulatory quality need to be spelled out** – the best strategies for embedding Better Regulation ideas into the decision-making process emphasise the need to make decisions only when benefits justify costs and encourage the selection of regulatory options that are least restrictive, are justified by the best available evidence, make greatest use of market forces, and promote investment in innovation. Recourse to novel or untried regulatory options, especially when used to manage risks, is viewed sceptically. Adoption of these principles will be of considerable value to the Commission's future strategy.

- **Synergies with the production and provision of scientific advice must be nurtured** – the success of the Better Regulation strategy will depend, to a significant extent, on basing decisions on the best available knowledge and evidence. Within the Commission's toolkits this is, in general, acknowledged. However, if this goal is to be achieved than new 'horizontal' standards for the evidence used in scientific assessments need to be introduced, along with improved institutional structures to develop and enforce them.

  At the same time, a new approach is needed to ensure that the most eminent and relevant experts undertake scientific assessments. Selection of experts should be based on modern understandings of bias, and of the wide range of conflicts of interest (including ideals, beliefs, ideologies, political associations, and financial benefits) that cause it.

  Existing EU-level standards and guidelines for the use of scientific evidence to manage risks lags global best practices. Findings from internationally respected science that meets the demanding standards of the scientific method, derived from world-leading scientific assessment processes, must be the principal basis for making risk management decisions. Ensuing this occurs is one of the biggest challenges facing the Commission's Better Regulation strategy.

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

European Risk Forum

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of the risk management issues at EU-level.

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 decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

The Forum believes that:

- High quality risk management decisions 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, cost, benefits, and legitimacy of different policy options (risk management);

- Risk management decision-making processes should ensure that outcomes are capable of meeting agreed social objectives in a proportionate manner;

- Risk management decisions should minimise negative, unintended consequences (such as new, unintended risks, economic losses, reduced personal freedoms, or restrictions on consumer choice); and

- The way in which risk management decisions are made should be structured, consistent, non- discriminatory, predictable, open, transparent, evidence-based, legitimate, accountable, and, over time, subject to review.

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.

The Forum works with all of the EU's institutions to promote ideas and debate. Original research is produced and is made widely available to opinion-formers and policy-makers at EU-level. 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. Indeed, direct engagement with opinion-formers and policy-makers, using an extensive programme of conferences, lunches, and roundtables, is a feature of the Forum's work.

The ERF is supported principally by the private sector. The ERF 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 ERF's work.

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