European Risk Forum – Monograph

Risk management and the EU's Administrative State: Implementing Law through Science, Regulation and Guidance

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Foreword

Today, there is a worrying lack of trust in the EU's institutions amongst citizens. Nationalistic and populist movements challenge our distinctive values. Citizens feel increasingly alienated from the decision-making processes of the EU, and too many no longer believe in its capacity to address their concerns and to resolve their problems.

Whilst this is, in part, a consequence of the gulf between the EU's aspirations and national political and socio-economic contexts, it is also the result of a lack of understanding about the way in which decisions that directly shape the freedoms, rights and behaviours of citizens are taken by the EU's institutions. Without a considered political debate, an Administrative State has emerged at EU level, creating a new relationship between citizens and the EU. Implementation of complex laws, particularly those that seek to manage risks, increasingly takes place through centralised institutions and processes. Yet citizens, although directly affected by the decisions made by the EU's Administrative State, know little about how decisions are made. Numerous technical bodies are involved using fragmented and non-transparent procedures and mechanisms to shape hundreds of, often quite controversial, decisions each year, the scale and significance of which are all too often overlooked.

Moreover, it is the "EU Administrative State", which embodies the growing powers entrusted to the public administration when it comes to determining and implementing measures aimed at protecting our health and safety as well as the environment. The existence of an Administrative State at EU level is not a problem per se. Most modern governments have developed forms of regulatory implementation through the central executive function. In the EU, however, this has occurred without a proper design, often in a piecemeal, inconsistent, and inefficient manner. It is the governance of the EU Administrative State that concerns us.

With this Monograph, the European Risk Forum sets a new agenda to further advance the Better Regulation strategy of the EU institutions. It maps out the main features of the EU Administrative State used to implement measures to manage possible harm from technology and from our way of living. It highlights the governance shortcomings that all too often undermine the predictability and proportionality of those measures. And, it illustrates the impact of these weaknesses on incentives to innovate and, ultimately, on

the ability of the EU to deliver and achieve the objectives of a prosperous, sustainable and sustained economy where citizens are protected from risks.

The Monograph identifies existing areas of good practices. It builds on them to set out comprehensive recommendations for a better-governed system that leverages high-quality science, protects procedural rights, emphasises the need for proportionality in implementation decisions, and considers risks and opportunities when pursuing our societal goals.

The recent European elections have renewed the European Parliament's composition. The new President of the European Commission has already indicated the main parameters of an ambitious vision for Europe. With this further contribution, "Better Administration" becomes the natural complement to the traditional EU Better Regulation approach – a necessary recalibration that bears great potential for Europe's economy and society.

We trust that these ERF ideas will help shape the debate around the future of the EU.

Howard Chase
Chairman
European Risk Forum

Dirk Hudig
Secretary General
European Risk Forum

Executive Summary

1. EU Administrative State and Risk Management

One of the most important challenges facing the new European Commission is to create greater trust with citizens through better administration, more transparency, better consultation, and feedback. It will require, amongst other changes, a major reform of the governance of the EU Administrative State, the principal means through which complex risk management laws, affecting most citizens and businesses, are implemented.

Since the end of the Second World War, governments in most OECD countries have assumed responsibility for managing major economic and social problems, responding to the concerns and desires of their citizens. Achieving these new, complex policy goals increasingly demands extensive primary legislation combined with implementation processes that require countless technical decisions on a daily basis, frequently involving rule-making or adjudications, that affect rights, freedoms, and behaviours. Within this context, the executive function of government is endowed with extensive powers, often weakening the traditional separation of powers, between executive and legislature, designed to protect citizens.

To meet these demanding requirements a new branch of government has emerged within the executive function: the so-called "Administrative State".

Over the last twenty years, an Administrative State has also emerged at EU level. There has been a major increase in direct administration and regulation by the EU institutions.

Within this new context of government activity, management of risk is one of the most important policy areas regulated through the EU Administrative State. This reflects a desire for higher standards of protection; a concern to strengthen the Single Market; a general expansion in the scope of risks managed; a focus on potential harms facing users of technologies; and, an emphasis on management of social concerns rather than risk reduction.

In response to these changes in risk management responsibilities and goals, new legal and institutional strategies have emerged to implement legislation. Specifically:

- **Centralised risk management processes and laws**, establishing legislation through regulations and making implementing decisions for the management of risks at EU level (rather than using directives to coordinate action in Member States);

- **Growth in the use of substantive guidance:** a form of soft law that frequently embeds risk assessment assumptions and risk management options when clarifying legal, procedural, and compliance requirements;

- **New centralised EU institutions, most notably risk assessment agencies**, that play a role in issuing substantive guidance, overseeing scientific assessments, and making draft risk management proposals;

- **Growth in comitology**, expanded to encompass the large number of formal rule-making and adjudication decisions needed to implement new, ambitious risk management laws; and,

- **Continued involvement of EU Member States** both to provide technical and scientific capacity for scientific assessments and licensing processes, and to oversee, through involvement in comitology, the Commission's use of implementing powers.

The impact of these new implementation mechanisms on the reduction of risk or on incentives to innovate is little understood. Yet, increasingly, it is these implementation processes, and the decisions they generate, that have the greatest impact on the standard of protection enjoyed by citizens and the natural world and, because they affect incentives to innovate, on sustainable growth. Finally, this new approach to the management of risk poses important challenges for governance, because of its reliance on an expanded and more powerful EU Administrative State.

2. EU Governance of the Administrative State

The characteristics of its Administrative State pose major governance challenges for the EU. Implementation of complex laws, especially those used to manage risks, requires large numbers of adjudication and law-making decisions by the executive function, potentially weakening the separation of powers. At the same time, the scale and

complexity of executive decision making may challenge the rule of law. Procedural rights are challenged too, because of the imbalance of power between affected parties and the EU's executive function. And, standards of good administration are threatened because the EU's Administrative State has developed piecemeal. Other challenges include ensuring overall policy coherence, managing regulatory overlap, and preventing regulatory capture.

There is no single solution to these challenges. Some steps have, however, been taken to strengthen governance. These include political initiatives focusing on design and management of comitology procedures and on the governance of agencies; decisions by EU Courts to place some limits on the way in which EU institutions make decisions; and, the Commission's focus on the entire policy cycle in the Better Regulation agenda.

Despite these improvements and initiatives, major weaknesses in the governance of the EU Administrative State remain unresolved. These major weaknesses are listed hereafter.

Lack of evidence of a systematic understanding within the EU institutions of the scale, nature and importance of the EU Administrative State and consequent lack of political commitment to establishing an overall governance framework.

- Lack of a single, comprehensive law of administrative procedures (or equivalent) at EU level.

- Judicial review by the EU courts not resting on a framework of procedural standards to match the increasing power and scale of the Administrative State.

- Major deficiencies in the development, scope, and powers of administrative appeals processes.

- Focus on the legislative process rather than the implementation process within the Commission's Better Regulation policy. This is trapped conceptually in a model of EU law-making that devolves implementation to Member States, rather than recognising the emergence of a powerful and extensive EU Administrative State.

- Major gaps in the coverage of the Better Regulation policy that limit its potential to strengthen the governance of the EU Administrative State.

3. Nature of the EU Administrative State

Implementation of risk management measures through the EU Administrative State takes place using a two-stage process. In the first stage of the process (**Assessment of Evidence and Preparation of Draft Measures**), a number of different institutional actors and procedures are coordinated by the European Commission to assess available evidence, principally science , and to prepare proposed risk management measures.

Unlike many other governments in the OECD area, there is no common model for the assessment of evidence and preparation of draft measures through the EU Administrative State.

In the second stage (**Implementation of Measures**), three principal EU Administrative State mechanisms are used to implement draft risk management measures: standards; comitology; and, substantive guidance.

3.1. Assessment of Evidence and Preparation of Measures

Over the last twenty years, the EU institutions have taken a number of initiatives to try and improve the quality of the processes used to assess evidence and prepare draft risk management measures. New agencies and bodies have been established; a number of existing assessment and preparation processes have been reformed; and good practices have been encouraged in a number of different areas.

Despite these improvements, there are continuing problems with the EU's institutions and the processes used to assess risks and prepare draft risk management measures. There is a clear lack of consistency in performance and quality. In too many cases, approval processes are slow or unpredictable; standards of scientific integrity are not adequately respected; proposed risk management measures are poorly informed or disproportionate; and procedural rights are insufficiently protected. Standards set by global peers are not matched on a systemic basis.

Other weaknesses, related to governance, further erode the quality of the initial stage of implementing risk management laws. Procedural rights are not easily protected because of major gaps in administrative appeals procedures, including the exclusion of opinions of scientific assessments from the scope of reviews. Involvement of affected parties is unduly limited because of the inadequate provision of scientific hearings. And, there is a lack of institutional responsibility for identifying and resolving regulatory overlaps.

3.2. Implementing Mechanisms – Comitology

Comitology continues to grow in importance as a mechanism for adopting large numbers of legally-binding implementation measures, whilst at the same time continuing to provide legislators with a mechanism for overseeing the actions of the Commission.

It has delivered a number of important benefits. These include: adopting into law large numbers of adjudications quickly; facilitating rapid adaptation to scientific change; easing access to the Single Market; maintaining political commitment; and, strengthening governance.

Despite these benefits, comitology has major structural weaknesses:

- Continued barriers to meaningful input by the public;
- Absence of formal "public dockets" where all information relied on is disclosed;
- Ability of decision-makers to rely on information that is not publicly available;
- Ability of decision-makers to rely on input from "experts" whose appointment is not subject to defined standards or review;
- Limited obligation to explain the legal and factual bases of decisions;
- Significant constraints on the ability of EU courts to meaningfully review decisions because there is no clearly defined factual or technical record;
- Unpredictable and inconsistent outcomes;

- Differences in scientific or technical expertise amongst Member States; and,
- Reinterpretation of secondary legislation circumventing the legislative process.

3.3. Implementing Mechanisms – Substantive Guidance

Substantive guidance provides regulators with a critical mechanism for structuring the way in which a wide range of risks are assessed and for delivering risk management outcomes. A form of soft law, it clarifies the meaning or scope of laws or defines the technical requirements that businesses must meet, if their products or materials or services are to satisfy standards of safety, quality or efficacy.

Used well, substantive guidance provides regulatory certainty; facilitates the implementation of poor quality or complex legislation; enables regulators to respond rapidly to scientific or technical change; and provides an alternative to new technology-specific laws.

The extensive role of substantive guidance in the implementation of risk management laws is, however, little understood.

Whilst substantive guidance is, at its best, a powerful mechanism for ensuring high-quality implementation, its use in the framework of the EU Administrative State reveals important weaknesses. Its quality varies and there is no systematic mechanism to enforce quality standards. It is a hidden form of rule-making because it often embeds assumptions about social acceptance of risk or ways to manage potential harms. On too many occasions, it is used to embed the Precautionary Principle into risk assessment, which is contrary to the European Commission's criteria for applying precaution. It provides a means to revise secondary legislation without involvement of legislators. And, regulatory impacts are largely overlooked or not understood when substantive guidance is developed.

4. Regulatory Impacts

4.1. Benefits

Citizens, the EU institutions and businesses benefit from a well-governed EU Administrative State that makes high-quality implementation decisions. Specifically:

- Better decision-making is facilitated, limiting the extent of "regulatory failure" and hence increasing the socio-economic benefits of public policy (jobs, wealth, security, safety, choice, quality of life);

- The legitimacy of the EU institutions is underpinned by strengthening the rule of law, delivering higher standards of protection without eroding incentives to innovate, and, complementing existing reform initiatives; and,

- The EU becomes a more attractive location for investment and innovation.

4.2. Negative Outcomes

Whilst a significant proportion of the decisions taken through the EU Administrative State to implement risk management laws are of high quality, too many have a negative impact. Poor quality decisions are characterised by regulatory failings of time, cost, precaution, proportionality, and uncertainty, and, over time, generate a series of negative regulatory outcomes for Europe and its citizens. Specific problems include:

- **Negative risk-risk outcomes** – increase in net risk;

- **High levels of defensive R&D** – diversion of resources away from new technologies, loss of access to existing "upstream" technologies;

- **Increased capitalised development costs** – reduced investment in innovation, delocalisation away from the EU, retention of old technologies, lower product availability, restructuring;

- **Loss of access to technologies** – cut back in innovation, loss of downstream employment and wealth, loss of social benefits of new ideas;

- **Reduced business sustainability** – restructuring, loss of employment, high adjustment costs; and,

- **Reduced market attractiveness** – reallocation of capital geographically, less innovation, fewer new ideas, retention of old technologies, less dynamism.

Taken together, these negative regulatory outcomes pose challenges for the European Union. They reduce incentives to invest in innovation and erode returns from markets and existing investments. This threatens employment and prosperity, and makes it more difficult for Europe's citizens to enjoy the social benefits of risk-taking. Instead, there is the possibility that the EU will become locked into a declining stock of old technologies unable to achieve its wider social aspirations. A further challenge is the failure to reduce net risk.

5. Conclusions

Steps have been taken by the EU institutions to strengthen governance of the Administrative State and to improve the consistency and quality of implementation processes and decisions. Many of these reforms have been successful and are to be welcomed.

Despite this, more needs to be done. In too many cases, decisions are disproportionate or unduly precautionary or unpredictable or take too long and impose unjustified costs. These are major failings. They can lead to an increase in net risk, less investment in innovation, disruption of value chains, erosion of business sustainability, and a fall in the attractiveness of the EU for global investors. Europe's citizens do not benefit from this, and such outcomes undermine the legitimacy of EU institutions.

There are obvious reasons for these failings. Governance exhibits significant failings, such as the lack of an EU Law of Administrative Procedures, inadequate political commitments to governing the Administrative State, and a failure to establish procedural rights. There is, moreover, no common model for the assessment of risk and preparation of risk management measures, making it difficult to achieve consistent, high-quality decision-making. And, policy-

makers have not addressed the major structural weaknesses of comitology and substantive guidance that limit their effectiveness as high-quality implementation mechanisms.

Lying behind these explanatory factors are a series of more challenging underlying causes. Specifically:

- Development of the EU Administrative State has been piecemeal;
- Design of risk management laws has failed to take into account sufficiently the difficulties of making very large numbers of high-quality implementation decisions;
- Inadequate consideration of a major mismatch between the ambitions of risk management laws and the availability of EU technical and scientific resources;
- Major changes in the risk management philosophy of the EU have made it more difficult to make high-quality implementation decisions;
- Too many scientific assessments, and the risk management measures they inform, continue to be unduly influenced by outdated scientific knowledge and concerns;
- Lack of awareness about the nature of implementation decisions has impeded the process of governance reform; and,
- EU institutions continue to conceive of the implementation of risk management laws within the framework of an outdated model of law-making.

6. Recommendations

This monograph identifies more than 20 reforms. They build on many good practices and initiatives already present within the EU institutions. The reforms complement each other. Taken together, they target the underlying causes of the failings of the EU's approach to implementing risk management laws, along with weaknesses in implementing mechanisms, and the assessment and preparation processes and in the institutions that support them.

In the short-term (1-3 years), the following actions should be taken:

- The **Council of EU Ministers** should affirm its support for the greater use of proportionality in law-making at all stages of the policy cycle by, for instance, adopting dedicated conclusions.

- The **EU Legislature** should, building on the work of the European Parliament, develop and adopt a comprehensive Law of Administrative Procedures.

- The **EU institutions** should establish common decision-making processes and standards for risk assessment agencies. These should include pre-submission hearings; independent administrative appeals procedures with a wide scope of reviewable decisions (including scientific assessments) and extensive powers of redress; expert panels for scientific assessments; scientific hearings; and common standards for developing substantive guidance.

- The **European Commission** should revise the mandate of the Scientific Advice Mechanism to establish explicit and formal oversight functions to ensure the effective functioning of the entire scientific advisory system.

- The **Secretariat-General of the European Commission** should be made responsible for resolving problems of regulatory overlap, acting independently of regulating directorates or EU agencies.

- The **European Commission** should, in the form of a communication, define the meaning and usage of a proportionality principle.

- The **European Commission** should develop and adopt minimum standards for the quality, collection, validation, and use of scientific evidence that all directorates and agencies must respect. These could be set out, for instance, in a new decision.

- The **European Commission** should issue supplementary guidance that clarifies the role of the Precautionary Principle in decision-making. Such guidance should be based on the requirements of the existing communication and should make it clear that the Precautionary Principle should not be used to influence scientific assessments that form part of the process of understanding hazards or risks.

- The **European Commission** should revise the Better Regulation guidelines to strengthen further the focus on comitology and to encompass within their scope substantive guidance developed by the Commission and the EU risk assessment agencies.

- The **European Commission** should require greater use of Cost Effectiveness Analysis (CEA) when conducting ex ante impact assessments of proposed implementing measures.

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1. Introduction

1.1. Setting the Scene

Throughout most of the OECD area, implementation of complex risk management laws takes place primarily through the actions of centralised institutions and bodies using a range of decision-making mechanisms that collectively form part of an "Administrative State". Part of the executive function, this new form of government exercises extensive executive, legislative, and adjudication powers, reflecting the scale and complexity of modern implementation decision-making.

Increasingly, it is these implementation processes, and the decisions they generate, that have the greatest impact on the standard of protection enjoyed by citizens and the natural world and – because they affect incentives to innovate, allocation of capital, and operating efficiency – on sustainable growth.

At EU level, an Administrative State has emerged without any formal political commitment, policy statement, plan, or comprehensive legislative protection of procedural rights. Its decision-making institutions and mechanisms are the result of a piecemeal approach, reflecting different and separate policy objectives, and older implementation mechanisms designed to achieve different policy goals. Taken together, these changes have exposed major weaknesses in the governance of a significant part of the EU's institutions, affecting citizens and businesses.

One symptom of these failings is the systemic intermingling of political issues with scientific and technical evidence in implementation decision-making (Exhibit 1). When this occurs, transparency and accountability are undermined, along with other principles of good governance, most notably predictability and proportionality.

In part, the origin of these problems lies in a structural change in the EU's risk management policy. Complex and ambitious laws, designed to manage the usage of materials throughout the economy, to shape lifestyle choices, or to reduce low-frequency risks, have emerged in response to social concerns. Risk reduction has been replaced by wider socio-political aspirations as the purpose of risk management laws.

EXHIBIT 1

EU ADMINISTRATIVE STATE AND SCIENTIFIC ASSESSMENTS – ILLUSTRATION OF FAILING GOVERNANCE

The inconsistency of the quality of scientific assessments, a critical process for making decisions that implement complex risk management laws, illustrates the failings that emerge from a poorly managed EU Administrative State.

Whilst some assessments used to guide EU decision-making processes meet world-class standards, too many do not. The consequences are significant. Low-quality studies that fail to meet the standards of the scientific method unduly influence committee opinions, because of the lack of binding quality guidelines. Assessments reflect hypothetical exposures or untested theories, again because of the lack of binding guidance for the conduct of scientific committees. And, assessments are undertaken by experts who lack relevant knowledge or are inappropriately influenced by beliefs, ideals, ideologies or political commitments, because of the exclusion of academics that work with industry. This final problem is emblematic of weak governance. It reflects a failure to develop and enforce guidelines that reflect a modern understanding of bias, and the complex material and non-material conflicts of interest that cause it.[1]

To meet these new, demanding requirements, governments take countless technical decisions on a daily basis often involving rule-making or adjudications[2] that affect the rights, freedoms, and behaviours of individuals and businesses. Within this context, the executive function of government is frequently endowed with extensive powers, often weakening the traditional separation of powers designed to protect citizens and corporations from poor quality or arbitrary decision-making.

1 These issues are considered more fully in European Risk Forum Monograph "Scientific Evidence and the Management of Risk" (2016).

2 In this context, the term "adjudications" refers to legally-binding case-by-case risk management decisions dealing with individual products, articles, or substances. Typical decisions include hazard classifications, usage restrictions, bans, listings, entries to positive lists, product approvals, and licence renewals.

At EU level, new forms of rule-making have been introduced and the use of existing ones expanded, mixing together soft law (substantive guidance), legally-binding implementation measures made using comitology procedures, and technical or environmental standards.

The impact of these implementation mechanisms on the reduction of risk or on incentives to innovate is, however, little understood. Too often they have been used without a full understanding of costs and benefits or without being supported by a credible intervention logic. This can trigger high levels of defensive R&D, extended costs of developing new products, reduced access to markets, loss or stigmatisation of materials and technologies, or increases in net risk through the process of risk-risk trade-offs.

Despite major efforts by the EU institutions to develop a comprehensive Better Regulation strategy, there continues to be limited awareness amongst opinion-formers and policy-makers about the existence of an Administrative State at EU level, its scale and nature, its impacts on citizens and businesses, and its governance weaknesses. This needs to change.

Urgent and systematic action is needed to reform governance of the EU's Administrative State, thereby enhancing institutional efficiency, strengthening procedural rights of citizens and businesses, and limiting regulatory failure. Such reform is a natural complement to the EU's Better Regulation strategy. It is also a means of strengthening the confidence of citizens in the relevance, effectiveness, and legitimacy of EU institutions. Good governance enhances the transparency of decision-making and ensures that implementation decisions are justified by credible and robust evidence, reduce net risks, deliver proportionate protective measures, and avoid undermining incentives to innovate.

1.2. Objective and Scope

This monograph, by the European Risk Forum (ERF) highlights, for the first time, the nature, scale and importance of the EU Administrative State and places it clearly within the scope of the EU's Better Regulation Agenda.

The monograph assesses some of the challenges to good governance of the EU Administrative State, and examines the impact of its implementation decisions on the

effective management of possible harms from technologies[3] or lifestyle choices to human health, public safety, and the environment. Finally, it seeks to promote the application of modern standards of governance to all parts of the EU Administrative State, and to develop a coherent set of recommendations for reform.

The insights and ideas set out in this monograph are an integral part of the ERF's work on scientific evidence and the management of risk, regulatory process management, risk management policy, better regulation, and innovation.

Reflecting the wider goals of the ERF, this monograph focuses on the public management of risks to human health, public safety and the environment posed by lifestyle choices or technologies. It focuses on implementation decisions, using substantive guidance or comitology, made through the EU Administrative State to manage these risks.

Technical or environmental standards, whilst widely used to manage risks, are not included within the scope of this monograph.[4]

1.3. Methodology

The findings, conclusions, and recommendations set out in this monograph are the result of a programme of research carried out by the ERF project team in the first half of 2019.

The programme includes nearly 40 confidential, in-depth interviews with legal scholars, academics, leading lawyers, and experts from companies and business organisations from a wide range of sectors in the EU and the USA. A desk research exercise was also carried

3 When considering risk regulation, the term "technologies" refers to specific forms of technology, such as biotechnology, and to the range of ideas, characteristics, and functional properties embedded in substances and products.

4 The monograph does not consider the use of technical or environmental standards to manage risks. These are important implementing mechanisms but they do not form part of this analysis. In most cases, EU risk management decisions are made using the so-called "New Approach", whereby essential safety and performance requirements are specified in secondary legislation and voluntary, standard-setting bodies draw up detailed guidance specifying how specific products or activities comply with them. Conformance with guidance is often determined by approved testing organisations. Historically, this approach has delivered high-quality decisions because of the involvement of relevant experts in the development of guidance and product-specific standards. Use of voluntary standards has also facilitated rapid and flexible adaptation to technical or scientific changes. Things are, however, evolving. Development of environmental standards for products poses additional challenges, for example, some of which have been resolved by political choices, creating opacity, limiting the influence of robust evidence, establishing uncertainty and triggering negative unintended consequences.

out. It reviewed academic literature, EU policies and guidance, and government policies from different parts of the OECD area.

Alongside these sources, the project team examined the findings of research carried out by the ERF over the last decade. Over this period, the ERF has published a series of research papers and convened meetings of the Risk Forum that have examined a series of issues of relevance to the nature and importance of the EU Administrative State.[5] The findings developed in those publications have benefitted from the insights of senior officials from several policy directorates of the European Commission and EU risk assessment agencies, members of the secretariat of the European Parliament, as well as world-leading academics.

The findings are also informed by research undertaken for the ERF Monograph "Scientific Evidence and the Management of Risk" (2016), including more than 60 confidential, in-depth interviews with legal scholars and eminent scientists from the EU and the USA, scientific advisers and government officials in EU Member States, senior officials from several policy directorates of the European Commission and from EU risk assessment agencies, members of the secretariat of the European Parliament, and experts from companies and business organisations in the EU and the USA.

1.4. Structure

In the first part of the monograph (Chapter 2), the scale and importance of the EU Administrative State is examined. It focuses on risk management and its importance as a domain of public policy. It shows how the EU's traditional model for managing risks, based on decentralised decision-making by Member States, has been progressively superseded by a new, "centralised" approach. It examines the main elements of this new approach to managing risks, highlighting changes in secondary legislation, the emergence of new centralised policies and bodies (coordinated by the Commission) for assessment of risks and preparation of measures, and the use of comitology and substantive guidance as implementing mechanisms. It finishes by developing a possible rationale for these changes, and considers some of the governance challenges that have emerged.

5 These include substantive guidance, comitology, risk assessment agencies, risk-risk trade-offs, regulatory overlap, EU Law of Administrative Procedures, regulatory and policy coherence, links between regulation and innovation, scientific integrity, and dynamic impacts of regulation such as defensive R&D, capitalised development costs, stigmatisation, and value chains and technology.

Chapter 3 considers the governance of the EU Administrative State. It identifies potential structural challenges and sets out a framework of political commitment, legislation, judicial review, regulatory policies, and oversight that, taken together, contribute to good governance of the Administrative State in selected OECD countries. This framework provides the basis for an initial review of the governance of the EU Administrative State.

Chapter 4 explores in more detail the nature of the EU Administrative State used to implement risk management laws. The review highlights and examines a two-stage decision-making process. In the first stage, the Commission coordinates a wide range of different bodies and processes to assess risks and to prepare draft risk management measures. Central to this is the process of scientific assessment.[6] In the second stage, substantive guidance (a form of soft law) and comitology are used as implementing mechanisms. Strengths and weaknesses of assessment and preparation bodies and processes, substantive guidance, and comitology are examined.

Chapter 5 focuses on some of the key impacts of the EU Administrative State. It highlights the risks of regulatory failure from poor quality implementation decisions and the importance of procedural rights throughout the decision-making process for public trust in the effectiveness and legitimacy of EU institutions. The chapter focuses on the importance for citizens of efficient, high-quality risk management decisions, and recognises that a failure to achieve this can lead to no reduction in net risk (risk-risk trade-off), unintended negative economic consequences, loss of the benefits of technologies, and no improvement in protection. In the final part, it examines the impact of implementation decisions on incentives to innovate.

In the final parts of the monograph, conclusions are set out (Chapter 6), along with recommendations for reform (Chapter 7).

6 Scientific assessments are evaluations of a body of scientific or technical knowledge that typically synthesise multiple factual inputs, data, models, assumptions and/or best professional judgements to bridge uncertainties in the available information. These assessments include, but are not limited to state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterisations of substances; integrated assessment models; hazard determinations; or exposure assessments. (Source: derived from a definition used by the US Office of Management and Budget.)

2. The EU Administrative State and Risk Management

2.1. Administrative State – Origins and Characteristics

Public risk management is one of the most important ways in which governments solve problems and meet the expectations of their citizens. It encompasses a range of policy objectives, most notably creating the conditions for economic prosperity by managing risks to trade and investment, protecting workers from the impacts of economic activity and urbanisation, and protecting citizens and the natural world from risks posed by technologies and lifestyle choices.

From its emergence as a public policy priority in the eighteenth and nineteenth centuries, governments have pursued risk management objectives through a complex multi-stage approach. Framework legislation, derived through a political process, sets out the social goals to be achieved, identifies the hazards to be controlled, defines the social acceptance of risk, and articulates the principal means by which the law will be implemented. Governments then use a number of processes, institutions and implementing mechanisms, many of them centralised, to implement legal requirements and to deliver goals set out in primary law.

Indeed, part of the origin of the Administrative State lies in the need for governments to directly employ experts needed to make the complex adjudication decisions that are required to implement risk management laws. Since the nineteenth century, for example, factory inspectors have made countless, heterogeneous decisions to manage risks posed by production technologies.

Since the end of the Second World War the role of government has changed fundamentally in most OECD countries. Governments have assumed responsibility for managing major economic and social problems, responding to the concerns, desires, and aspirations of their citizens. This includes taking responsibility for managing the impacts of risks from economic activity, urbanisation, technologies, and lifestyle choices. In many instances, achieving these new, complex policy goals requires extensive primary legislation combined with complex implementation processes that require the executive function to take countless decisions on a daily basis.

To meet these demanding requirements, a new branch of government has emerged in most OECD countries: the so-called "Administrative State" (Exhibit 2).

The nature and development of the Administrative State reflects a number of factors. There is an evident need for expanded technical, scientific, and bureaucratic capacity because of the number of implementation decisions that governments must make. By centralising these decision-making processes, governments seek to develop expertise in understanding legal requirements in complex contexts, as well as, ideally, achieving uniformity of interpretation of legal requirements and in their implementation. In response to evolving public demands, the creation of the Administrative State also provides a mechanism for enhancing the efficiency, impartiality, and objectivity of decision-making, thereby enhancing legitimacy.

Looking across the OECD area, it is possible to identify a number of common characteristics of the Administrative State, including:

- **Reconfiguration of separation of powers** – whilst the Administrative State is clearly part of the executive function, it is frequently endowed with legislative and adjudication powers because of the need to make large numbers of decisions when implementing complex legislation. This weakens the traditional separation of powers, and associated checks-and-balances, designed to protect citizens from poor quality or arbitrary decision-making, posing challenges for governance and for the rule-of-law.

- **Complex implementation mechanisms** – a mix of soft law (substantive guidance) and legally-binding implementing rules are used to achieve compliance with the typically wide-ranging and complex requirements of legislation. This creates challenges for protecting the procedural rights of those affected by implementation decisions and ensuring that high-quality regulatory processes are used to inform decision-making.

- **Powerful centralised institutions** – centralised institutions and processes are used to assess problems and to prepare implementation measures. Most notably independent, sectoral agencies have been established in parallel with the Administrative State, which provide technical, scientific and bureaucratic capacity, as well as expertise. Whilst they can enhance transparency, consistency, harmonisation, and objectivity, contributing to public trust, agencies and implementing bodies may also create challenges for

governance, particularly in terms of the consistent application of regulatory process standards and the availability of administrative appeal procedures.

- **Partial sources of consent** – the legitimacy of the actions of the Administrative State does not rest on democratic processes, directly. Instead, it is exclusively based on its capacity to make decisions impartially and objectively and on its expertise in understanding problems and in designing solutions ("output legitimacy"). At its best, supporters argue that the Administrative State is better able than democratic institutions to implement laws because it is free from conflicts of interest or from "capture" by vested or political interests. This leads, it is argued, to more efficient government. Ideally, the Administrative State should act impartially, predictably, and according to what is foreseen in law. Achieving these goals poses challenges for governance, including ensuring that decision-making processes meet such standards.

- **Independent policy priorities** – architects of the development of the Administrative State argued that one of its strengths was the capability to adapt existing legislation, so as to respond better and more rapidly than democratic institutions to emerging policy priorities. Legislative requirements can be expanded, made more onerous, or revised without the involvement of law-makers using "hidden or disguised law-making" capacities embedded in regulations or statutory instruments, substantive guidance, and administrative discretion. The restraint of the utilisation of such powers poses a major governance challenge for law-makers in all OECD countries. Their use is also, arguably, inconsistent with the Administrative State acting predictably and according to law.

- **Impact on citizens and businesses** – decisions made through the Administrative State affect the behaviours and freedoms of citizens and businesses directly, reflecting the change in the role of the state in OECD countries over the last seventy years. Indeed, the Administrative State has become the most important way in which society interacts with the state. It is these law-making and adjudication decisions that primarily affect the quality of life enjoyed by citizens, including protection of safety, health, and the natural world, and that shape incentives to innovate. Within this context, it is important to protect procedural rights and to ensure that implementation decisions are of the highest quality. These are major governance challenges.

EXHIBIT 2

THE ADMINISTRATIVE STATE – WHAT IS IT?

Although the term "Administrative State" can be dated to the work of American political scientist Dwight Waldo in the 1940s, the conceptions that underlie it were debated and developed much earlier.[7]

Liberal and progressive scholars in the US, UK and Germany, for example, began in the final decades of the nineteenth century to examine ways of using the powers of the state more extensively and actively to manage the consequences of urbanisation and industrialisation. Faced with these challenges, a small number of progressive thinkers in the USA questioned the continued relevance for the public interest of the separation of powers and limits on delegation embedded in the Constitution, and sought to design ways to overcome them. In place of the protection of the absolute liberties of life, freedom, and property that formed the purpose of the US Constitution, such thinkers prized, in its place, the efficiency of an expert state, judged by its capacity to implement "good" decisions that citizens collectively were no longer able to make because of their exposure to the corrupting effects of markets and cities.

Drawing from the work of German sociologist Max Weber, amongst others, this group of liberals and progressives championed the emergence of more or less autonomous public administration able to implement laws, often by clarifying, expanding, and substantiating them with technical expertise, to adjudicate, and to serve as the first major point of contact between the citizen and the state.[8]

More recently, scholars of "new institutional economics" have conceptualised the emergence of a more extensive, expert, and autonomous public administration in terms of minimising transaction costs, enhancing the efficiency of organisations, and shaping institutional change.[9]

Today, because of the prominence and nature of the public administration in contemporary decision-making, the Administrative State is often referred to as the "fourth branch" of government.

7 Waldo D. "The Administrative State: A Study of the Political Theory of American Public Administration" (1948).

8 Peters G. and Pierre J. "Introduction: The Role of Public Administration in Governing", in Peters G. and Pierre J. eds. 'The SAGE Handbook of Public Administration' (2012).

9 North D. "Institutions, Institutional Change, and Economic Performance" (1990).

2.2. EU-level Administrative State

Over the last twenty years an Administrative State has also emerged at EU level. There has been a major increase in direct administration and regulation by the EU institutions, most notably in policy areas such as competition law, supervision of financial markets and related institutions, internal and external trade, and management of risks posed by technologies and lifestyle choices.

The growth of the EU Administrative State is the result of a number of factors. Some reflect the wider trends in government that all parts of the OECD have responded to, whilst others are specific to the European Union.

The legal scope of EU competencies has expanded significantly. At the same time, there is a growing recognition that protecting the Single Market is better achieved through centralised institutions making harmonised implementation decisions rather than using devolved decision-making. Greater centralisation of decision-making also provides a means, it is argued, to improve the "efficiency" of EU institutions by increasing capacity and expertise, whilst at the same time improving objectivity, consistency, and predictability (Exhibit 3). Over time, this is expected to strengthen legitimacy and reduce euroscepticism.

2.3. Public Management of Risk and the EU Administrative State

Within this new context of government activity, management of risk is one of the most important policy areas regulated by the EU Administrative State. This is the result of five factors.

First, it reflects a desire amongst EU citizens for higher standards of protection. Centralised institutions provide a means of meeting these aspirations.

A second factor is the aim of EU Member States to strengthen the Single Market through greater harmonisation, objectivity, and consistency of risk management decision-making. Historic experience with decentralised methods of managing risk suggests that these goals may be better achieved through centralisation of implementation.

EXHIBIT 3

KEY CHARACTERISTICS OF THE EU ADMINISTRATIVE STATE

Centralised secondary legislation – legislators have made increased use of direct EU laws (regulations) to control implementation and enforcement, rather than using directives to coordinate activity in Member States.

Extensive rule-making – regulatory decisions made using comitology, one of the principal forms of implementation used by the EU Administrative State, have become the most important source of EU rules. **In 2017, for example, more than 1,800 implementing laws were adopted using the various comitology procedures. Almost 270 active comitology committees, made up of experts from Member States, supported this process of law-making in 2017.**[10]

Growth in EU agencies – a multiplicity of agencies have been set up on a case-by-case basis in response to different policy needs, and undertaking different tasks. **In 2017, there were more than 35 EU agencies, employing more than 9,000 people, with a total budget in excess of € 2 billion.**[11] Some, such as EAR, GSA, GFCA, FRONTEX, and EUROPOL, are in charge of operational activities, whilst others, such as EEA, gather and analyse information. Another group, primarily EMA, ECHA, and EFSA, provide independent, science-based risk assessment, along with proposed risk management measures.

Networks of national regulators – one of the characteristics of the EU Administrative State is its heterogeneity, because it has been established in a piecemeal fashion responding to different policy priorities. An example of this is the continued involvement of Member States in the implementation of secondary legislation in certain policy areas. Networks of national regulators, coordinated by the European Commission, develop implementing rules and guidance for the regulation of privatised infrastructure, such as telecommunications and electricity generation and transmission.

10 European Commission "Report on the Working of the Committees during 2017" (COM (2018) 675 final).

11 European Parliament Research Service "EU Agencies, Common Approach and Regulatory Scrutiny: European Implementation Assessment" (2018).

Third, the EU institutions, along with governments in most other modern economies, have progressively expanded their responsibilities for managing the potential risks and maximising the potential benefits from technological progress. These responsibilities now encompass issues such as product safety, food safety, pharmaceuticals, usage and production of organic and inorganic chemicals, consumer goods, emissions from production facilities, biocides, motor vehicles, occupational health and safety, crop protection products, novel foods, biotechnology, cosmetics, medical devices, and materials usage in electronics and electrical products. Most of the economy, and our way of life, is affected.

Fourth, as well as expanding the scope of risks managed at EU level, legislators have focused on risks posed by usage of materials rather than the impacts of production technologies. Recent legislation, such as laws to manage risks posed by the usage of chemicals, biocides, food ingredients, food additives, and crop protection products throughout the economy, requires a very large number of legally-binding regulatory decisions, as substances and their uses are dealt with on a case-by-case basis (Exhibit 4).

Finally, there has been a further change in the risk management strategy of the EU. It has shifted from mitigating well-understood risks posed by production technologies and a small range of products (such as pharmaceuticals) with the aim of achieving explicit improvements in human health and environmental protection, to using risk management laws to deliver wider social goals (such as a risk-free world), and to manage concerns and perceptions. This shift has led to a focus on small or non-existent risks and on the usage of materials throughout the economy. Managing these concerns requires a major increase in expertise and in bureaucratic, technical, and scientific capability because of the number of rule-making and adjudication decisions needed to implement legal requirements.

Alongside, this major expansion in the scope of risk management responsibilities and the significant change in the strategies to manage them, new legal and institutional strategies have emerged. Specifically:

- **Centralised risk management processes and laws** – as part of a general trend in most policy areas, as well as interventions to manage risk, EU legislators have made increasing use of regulations as a form of secondary legislation, focusing on making implementing decisions for the management of risks at EU level, rather than using directives to coordinate action in Member States.

EXHIBIT 4

SCALE OF THE EU'S RISK MANAGEMENT RESPONSIBILITIES – EXTENSIVE AND LITTLE UNDERSTOOD

The scale and ambition of the EU's risk management responsibilities are vast. It is, however, little understood. It encompasses many thousands of substances and their uses.

REACH, the EU's law regulating the **use of chemical substances** throughout the economy, will require, it is estimated, risk management measures for each use of more than 80,000 substances, for instance. And, moreover, the scale of usage remains to be fully determined.

Food safety laws provide an additional example. Laws regulating risks posed by **food, animal feed, and crop protection** products cover more than 8,000 substances.

The adjudications needed to manage these risks expand the scrutiny, powers, and impact of the EU Administrative State, and stretch its capacity for efficiency and for delivering proportionate, high-quality decisions.

- **Growth in substantive guidance** – policy-makers have sought increasingly to manage the usage of materials throughout the economy, and to reduce low-frequency risks, whilst, at the same time, pursuing ambitious societal goals. Pursuit of these ambitious goals has led to lengthy, ambiguous and complex secondary legislation that requires extensive substantive guidance (an informal type of rule-making) if it is to be implemented effectively. Substantive guidance clarifies legal requirements, sets out procedural requirements, and establishes what affected entities must do in order to comply with the law. It also embeds risk acceptance assumptions and risk management requirements (Exhibit 5).

EXHIBIT 5

SUBSTANTIVE GUIDANCE – HIDDEN AND VOLUMINOUS REQUIREMENTS

The scale of substantive guidance is extensive and little known, often covering many thousands of pages for individual technologies, substances, or sectors.

Approvals for licensing new or existing **crop protection** products require compliance with more than 3,000 pages of substantive guidance, for example.

Licensing of new or existing **biocides** requires compliance with a similar scale of guidance of at least 3,000 pages.

Similarly, over 4,000 pages of guidance define the requirements that must be satisfied before a licence to import **genetically-modified crops** can be considered by regulators.

Regulation of the **veterinary medicine** industry provides a further example. Companies must comply with more than 5,000 pages of guidance, covering new product approvals and manufacturing, in order to manage risks.

- **New EU institutions** – the EU secondary legislation has established new bodies, most notably risk assessment agencies and independent scientific committees, to assist the implementation process. Although most of these agencies are primarily involved in risk assessment, they also play a role in rule-making and adjudications. Moreover, risk assessment agencies also issue extensive substantive guidance, some of which embeds assumptions about social acceptance of risk or ways to manage potential harms. This is a hidden form of rule-making. Alongside these activities, agencies advise the European Commission about the safety of materials or products on a case-by-case basis, directly intervening in the formal regulatory process.

- **Growth in comitology** – this is the traditional mechanism for providing legally-binding implementation measures but has been expanded to encompass the large

number of formal rule-making and adjudication decisions needed to implement new, ambitious, and wide-ranging risk management laws (Exhibit 6).

EXHIBIT 6

GROWTH IN COMITOLOGY – CHARACTERISTIC OF THE EU ADMINISTRATIVE STATE

With its origins in the 1960s, comitology provides a means for the Member States, and in some instances the European Parliament, to oversee the use of implementing powers by the Commission. It does, however, have major structural weaknesses.

One indication of the scale of importance of this implementing mechanism is that comitology committees supporting solely DG SANTE adopted over 800 implementing rules in 2017.[12]

- **Continued involvement of Member States** – the EU Administrative State has not been developed on a consistent basis. Its structure and nature reflect a piecemeal response to different risk management concerns, as well as the need to gain access to technical and scientific resources and to secure political commitment. In the light of these circumstances, Member States continue to play an important role in the implementation or risk management laws, although often their contribution is coordinated by the European Commission.

  Members States undertake scientific assessments to support hazard classifications or product approvals or licence renewals in a number of areas. When they act as "rapporteurs", for instance, they are responsible for undertaking scientific assessments. They also provide experts to take part in Technical Working Groups tasked with overseeing risk assessment or carrying out peer reviews. They are involved in agency governance and, through their role in comitology, in the preparation and adoption of risk management measures.

12 European Commission "Report on the Workings of the Committees during 2017" (COM (2018) 675 final).

Whilst there are clear advantages from involving Member States in the assessment and management of risks, there are also problems. The underlying rules of procedure for undertaking scientific assessments or product approvals or licence renewals, as well as the criteria for their involvement in decision-making, are neither uniform nor fully transparent. In too many instances their involvement in implementation processes leads to delays in decision-making, uncertainty of outcomes, and politicisation.

For a wide range of substances, materials, and technologies, risk management decisions made through the EU Administrative State now include:

- Restrictions and usage bans;
- Pre-market approvals for new or improved products;
- Licence renewals for existing substances;
- Emission or exposure limits for occupational health, worker safety, consumer safety and environmental impacts;
- Positive lists of approved ingredients;
- Guidance for production technologies and standards for manufacturing;
- Guidance for safety, quality, or efficacy testing requirements;
- Usage conditions;
- Hazard classifications; and,
- Public "blacklists" of products or substances of concern.

For businesses and citizens, these decisions, and their impact, have important implications for incentives to innovate, personal choice, and the level of net risk. In general, these impacts are not widely or fully understood.

This new approach to the management of risk poses important challenges for governance, because of its reliance on an expanded and more powerful EU Administrative State.

3. Governance of the EU Administrative State

3.1. Challenges

The characteristics of its Administrative State pose a series of important challenges for the EU's governance. Specifically:

- **Separation of powers** – in order to implement complex secondary legislation, the EU Administrative State, part of the executive function, makes large numbers of legally-binding adjudication decisions, as well as engaging in law-making through substantive guidance and comitology. Unless properly governed, this weakens the separation of powers: the traditional means of balancing the branches of government, so as to protect citizens against arbitrary or capricious decision-making by legislators or the executive.

- **Rule of law** – the reconfiguration of the separation of powers necessary for the effective functioning of the EU Administrative State, combined with the scale and complexity of decision-making processes it oversees, increases the possibility of administrative discretion and, in certain circumstances, challenges the rule of law. Problems include measures that are not in accordance with the law or contrary to constitutional rights or in excess of statutory jurisdiction. Measures may also breach key legal principles that define accepted aspects of the rule of law such as legal certainty, legitimate expectations, non-discrimination, proportionality or duties to state reasons or to comply with the EU Charter of Fundamental Rights. They may also be manifestly wrong or unsupported by substantial evidence.

- **Procedural rights** – the scale and complexity of the EU Administrative State has led to a situation in which citizens and businesses are faced increasingly with direct action by the EU's institutions. All too easily, this creates an imbalance of power, facilitates administrative discretion, and weakens legitimacy, unless parties affected by the actions

of governments have corresponding procedural rights, established by legislation, and access to the appropriate means to enforce them.

- **Standards of good administration** – implementation of complex legislation by the EU Administrative State challenges standards of good administration. Different decision-making processes make large numbers of law-making and adjudication decisions, making it difficult to ensure adherence to common standards. Problems include a lack of transparency and consistency; inadequate opportunities for public participation; reliance upon evidence not included in the public record; and a lack of independent administrative review.

- **Efficient government** – one of the ways that the EU Administrative State seeks to attain consent for its actions is by functioning as an "efficient" institution. In view of the scale of implementation activity and the piecemeal origins of the decision-making processes, this is difficult to achieve. Problems emerge if decisions are slow or unpredictable or partial or disproportionate, of if decision-making processes lack transparency.

- **Policy coherence** – when making very large numbers of implementation decisions using different decision-making processes, it is difficult to identify conflicts between existing legislation designed to serve older social requirements and new policy goals. Too often, implementation decisions frustrate initiatives designed to achieve different public policy priorities. Management of risks using existing legislation may, for example, make it difficult to promote newer sustainability policies. Over time, this becomes a form of regulatory failure.

- **Regulatory overlap** – pursuit of increasingly ambitious risk management goals using the EU Administrative State leads, in some instances, to conflicts with other older risk management laws and their implementation. Indeed, there are instances where the same risk is regulated by more than one risk management law. This is regulatory overlap and it is a feature of complex risk management contexts in most developed economies. Problems emerge when overlaps create uncertainties or additional unintended consequences or additional risks. In some instances, they may reduce protection and diminish incentives to innovate.

- **Regulatory capture** – weaknesses in the traditional means of ensuring that governments are subject to law and that citizens are protected from arbitrary actions by legislators or the executive, lead to administrative discretion, opacity of decision-making, and regulatory capture by vested interests. At EU level, vested interests include Member States, businesses, and civil society organisations.

Resolving these complex governance challenges is difficult. There is no single or simple solution. It requires a mix of political, judicial, legislative, policy, and institutional measures.

3.2. Good Governance Practices

As a branch of modern government, a form of the Administrative State is present in most countries within the OCED area. All face similar governance challenges. Initial analysis of measures used in a number of countries within the OCED area, including EU Member States, reveals a number of good practices that, taken together, are used to manage the governance challenges set out above. The following is a list of these types of measures.

- **Political commitment** – there is a clear recognition at the highest levels of government of the scale, nature, and importance of implementing measures and institutions, and of their impact on personal freedoms, procedural rights, levels of risk, and incentives to innovate.

- **Legislative framework** – there is a law of administrative procedures (LAP) or an equivalent body of administrative law on executive law-making. An LAP is a law setting out how laws should be made. It is an essential feature of modern, democratic and effective government. It places legally enforceable limits on the way in which governments exercise their administrative powers, particularly the rule-making and adjudication decisions taken by the executive function to implement complex laws. It clarifies and protects the rights of businesses and citizens when governments take actions that affect them directly, establishing clear procedural due process requirements and strengthening judicial review. Finally, it enshrines in law the principles of good administration: transparency and consistency; public participation; public record; and accountability.

- **Judicial review** – implementation decisions, and the institutions that prepare and adopt them, are subject to independent administrative and judicial review to ensure that correct procedures have been followed, that decisions are substantially in line with authorising legislations, that decisions have been rationally based on the publicly available record, and that comments from the public have been taken into account. Judicial review should also uphold the wider rule of law, including breaches of legal certainty, legitimate expectations, non-discrimination, proportionality or duties to state reasons or, in the case of the EU, to comply with the EU Charter of Fundamental Rights.

  Finally, independent administrative appeals procedures are extensively available for directly affected parties during the assessment and preparation phase of implementation, and encompass a wide scope of reviewable decisions (substantive and procedural), as well as providing extensive remedial powers. The scope of such appeal procedures includes, moreover, the findings of scientific assessments.

- **Policy framework** – there is a clear and comprehensive regulatory policy that focuses on implementing measures, including substantive guidance. It sets out guiding principles. Measures should:

  - Protect human health, public safety, and the environment, whilst promoting innovation, economic growth, competitiveness and job creation.

  - Be based on evidence, including, where appropriate, the best available scientific evidence.

  - Ensure that benefits justify costs and that net risks are reduced.

  - Demonstrate, through a structured impact assessment process, a clear, legal, and evidence-based intervention logic; an understanding of costs and benefits, including unintended consequences, value chain and other dynamic impacts, risk-risk trade-offs and policy coherence; and, proportionality.

  - Seek the least burdensome form of intervention.

  - Promote predictability and reduce uncertainty.

- Be reviewed after implementation by a structured process of ex post evaluation that includes assessment of "horizontal" unintended consequences.

- Be produced by modern, transparent decision-making processes, including extensive opportunities for meaningful engagement with affected parties.

- **Institutional architecture** – institutions, directly reporting to the centre of government, are established that have clearly defined powers and adequate resources to exercise oversight and to ensure that implementing measures adhere to the standards and principles set out in the regulatory policy. There are also explicit, effective organisational and procedural mechanisms for resolving regulatory overlaps and for ensuring that scientific assessments adhere to agreed standards of scientific integrity.

3.3. EU Governance of the Administrative State

3.3.1. Political Commitment

At EU level, political interest in the implementation of laws primarily focuses on the transposition of EU law by Member States and "gold-plating" at national level. In contrast, attention to centralised implementation mechanisms by political leaders has been limited to two issues only – design and management of comitology procedures, and governance of agencies.

Comitology procedures provide a formal means whereby implementing measures are legally adopted by the EU institutions, whilst at the same time establishing political oversight over exercise of executive powers by the Commission. At its best, this oversight process forms one of the most prominent mechanisms governing decisions made by the EU Administrative State.

Political commitment to the exercise of control of comitology decision-making is set out in the Inter-Institutional Agreement adopted by the EU institutions in 2003 and renewed in 2016. The most recent agreement focuses on enhanced collaboration and transparency in deciding when to have recourse to the different comitology procedures set out in Articles 290 and 291 on the Treaty. It also acknowledges the importance of the Commission

consulting appropriately and gathering relevant expertise before elaborating implementing measures.

Alongside these joint political commitments, the Commission has taken some steps to try and improve the transparency of the comitology process. Reforms include the creation of a Register of Expert Groups, a Comitology Register, and a Register of Interest Representatives.[13]

An important additional area of political focus on the governance of the EU Administrative State is set out in the 2012 Inter-Institutional Joint Statement and Common Approach on Decentralised Agencies. This acknowledges that EU agencies have been established on a case-by-case basis with no overall vision of their role in implementing the European Union's policies. The statement sets out to rationalise and standardise the establishment, governance and functioning of the agencies, including the main risk assessment agencies (EMA, ECHA, EFSA). Progress reports were published in 2013 and 2015. Significant achievements include streamlining agency internal governance and organisation, establishing more transparent budgetary regimes, and enhancing the transparency and predictability of work programmes. A non-binding set of guidelines for the prevention and management of conflicts of interest in EU decentralised agencies was also issued by the Commission in 2013.[14]

Despite these improvements and initiatives, there is a lack of evidence of a systematic understanding within the EU institutions of the scale, nature and importance of the EU Administrative State and consequent lack of political commitment to establishing an overall governance framework. Specific problems include:

- **Lack of an overall political statement by the EU institutions recognising the importance of the EU Administrative State for citizens and businesses**, and setting out broad principles of governance.

13 See: https://ec.europa.eu/regexpert/; http://ec.europa.eu/transparency/regcomitology/index.cfm?do=implementing.home; http://ec.europa.eu/transparencyregister/publib/homePage.do.

14 See: http://europa.eu/european-union/about-eu/agencies/overhaul_en.

- **Failure to include implementing processes and mechanisms within the Inter-Institutional Agreement on law-making.** Substantive guidance and standards for decision-making processes or scientific evidence are not considered, whilst measures to reform the well-established weaknesses of comitology were overlooked.

- **Lack of focus within the Inter-Institutional Statement on Decentralised Agencies on establishing common principles and guidelines for scientific integrity; on bringing agency decisions, including substantive guidance and risk management recommendations, within the scope of the Commission's Better Regulation policy**; and, on establishing powerful, independent administrative appeals procedures in all agencies able to examine substantive and procedural issues, including scientific assessments, and with extensive remedial powers.

  Efforts by the EU institutions to consolidate and streamline the governance, functioning, and procedural framework within which EU agencies operate, outlined in the 2012 Joint Statement and Common Approach, do not address the scale and nature of the EU Administrative State. They have not, moreover, been conceived or implemented as a complementary part of the EU Better Regulation Agenda.

- **Undue emphasis on financial issues in the Commission's non-binding guidance on managing conflicts of interest, and a lack of recognition of the wide range of conflicts that contribute towards bias.** The modern understanding of bias recognises that it results from a range of conflicts of interest, including personal factors, financial concerns, and ideals or ideologies (values). Disproportionate attention to financial concerns, identifying it as the only source of conflict of interest, tends to exclude academics with relevant knowledge of hazards and risks, whilst failing to recognise the negative impact of pre-determination (a consequence of values-based conflicts) on the quality of scientific assessments, as well as on perceptions of impartiality.

  Existing Commission guidance, if implemented without revision, is likely to contribute to a reduction in the availability of expertise to support the assessment of risks and preparation of risk management measures.

3.3.2. Legal Framework

Unlike most governments throughout the OECD area, the European Union does not have a single, comprehensive law of administrative procedures (or equivalent).

As a result, institutions and bodies at EU level operate within a fragmented framework of administrative procedures, referring to the general principles set out in the Treaties; provisions in the Charter of Fundamental Rights; case law from EU courts; specific ad hoc legislation, such as Regulation 1049/2001 on access to documents; codes of good behaviour (such as the Ombudsman's code); limited judicial remedies; and administrative guidelines, such as standards for consultation, impact assessment, use of the Precautionary Principle, evaluation, and the collection and use of expertise.

Many of these standards were informed by the European Commission's 2001 White Paper on Governance, and supporting preparatory work. Whilst they represent a major improvement in regulatory process management and have helped improve the way in which legislative and regulatory decisions are taken, they are soft law requirements and do not provide legally enforceable procedural rights.

Because of the growth in scale and importance of the EU Administrative State, citizens and stakeholders are faced increasingly with direct action by the EU's institutions without having corresponding uniform procedural rights, set out in a single law, and the legal means to challenge them.

There are, however, sectoral procedural standards in a number of policy areas. For example, in competition law, strong enforceable standards have been created, partly in response to pressure and case law from the EC courts. In other areas, including decisions by risk assessment agencies, standards are all too often incomplete, inconsistent, and not enforceable.

Despite the presence in the Treaty of Article 298 providing a legal basis for a law of administrative procedures (LAP), citizens and stakeholders lack enforcement of uniform, coherent and transparent legally enforceable procedural rights when dealing with the EU Administrative State. In fact, they

enjoy different levels of protection depending on the source of administrative procedure in force. This is a major governance weakness.

The principal weakness is the lack of an EU-level LAP that sets out and makes enforceable the key principles of good administration (transparency and consistency; public participation; public record; and accountability); establishes clear, legally-binding procedural standards for each of the key principles of good administration; encompasses all principal implementation mechanisms; and, ensures clear judicial review standards.

An EU-level LAP is a natural complement to the Commission's Better Regulation strategy. A well-designed LAP would consolidate regulatory process standards; provide more robust evidence and processes to justify regulatory decisions; help achieve social goals more effectively whilst limiting unintended negative consequences; and, it would improve the quality of risk assessment and management. Finally, evidence from elsewhere in the OECD area suggests that a well-designed LAP reduces litigation and does not slow down the process of regulatory decision-making.

The European Parliament has promoted the introduction of a LAP at EU level, with support and advice from other institutions such as the European Ombudsman, and from academics (Exhibit 7).

3.3.3. Judicial Review

Decisions by EU Courts have, in a number of areas, helped to place limits on the way in which EU institutions make decisions, including implementing secondary legislation. The Courts have, for example, established important procedural standards as general principles of EU law. These include the right to be heard (public consultation); a duty of careful and full examination; access to documents; and a duty to give reasons. EU Courts have also demonstrated a willingness to review measures to ascertain that there is no manifest error, misuse of power, or abuse of discretion.

There has also been progress, through case law, in developing partial procedural standards for the use of the Precautionary Principle. Its use should not be justified, for example, on the basis of a purely hypothetical rationale.

EXHIBIT 7

THE COMMITMENT OF THE EUROPEAN PARLIAMENT TO AN EU LAP

Over the past two terms, the European Parliament has been active in advocating for comprehensive rules on good administration.

In 2016, the EP adopted a dedicated resolution calling for a new EU regulation constituting a general Law of Administrative Procedures. It underpinned this initiative with an EP European Added Value Assessment, an impact assessment, a public consultation, and various public hearings, as well as legal opinions and studies by leading European legal scholars.[15] Evidence from this range of sources concluded that an EU LAP would increase legal certainty significantly; allow cost savings from more efficient administration; better protect the public; enhance trust between citizens and the EU administration; reduce litigation; and increase legitimacy through better transparency and accessibility.[16]

The ERF contributed to the public consultation launched by the EP Legal Affairs Committee in 2018 – the first of its kind.[17]

Alongside this, there has been some limited progress to developing administrative mechanisms to appeal the actions of agencies. Specifically, a Board of Appeal has been established within ECHA.

Judicial review by the EU Courts has not created, however, a framework of procedural standards to match the growth in the power and scale of the Administrative State at EU

15 The ReNEUAL network has carried out extensive expert review and produced tailored model rules and explanatory notes. See: http://www.reneual.eu.

16 See: https://europarl.europa.eu/legislative-train/theme-union-of-democratic-change/file-eu-administrative-procedure; and http://www.europarl.europa.eu/committees/en/juri/eu-administrative-law.html?tab=Background.

17 European Risk Forum "Communication 18: European Parliament Public Consultation on General Rules for an Open, Independent, and Efficient European Administration" (2018). See: http://www.riskforum.eu/publications.html.

level. There also major deficiencies in the development, scope, and powers of administrative appeals processes as outlined hereafter.

- **EU Courts traditionally accept that the Commission exercises discretion when determining the scope of powers conferred on it.** In general, the Courts tend to allow the Commission to adopt all measures that are necessary or appropriate for the implementation of secondary legislation, provided they are not contrary to it.

- **EU Courts have unsystematically reviewed the factual findings underpinning an implementing decision, mostly limiting the substantive review to appraising whether the decision is "arbitrary" or rests on a "manifest error".** EU case law has not, therefore, developed a coherent standard of judicial review of factual determinations, nor an explanation of how the judge determines whether the administration had complied with such standards.

- **There are important gaps in the provision and powers of administrative appeal procedures.** In too many cases they are not available to affected parties, limiting the possibility of redress without formal proceedings in the EU Courts. Many agencies do not yet have such procedures, and they are not available for measures prepared without the support of decentralised agencies. Limitations on the scope and redress powers of existing procedures are further sources of weakness in governance of the EU Administrative State. Not all administrative appeal procedures allow affected parties to seek independent examination of procedural and substantive failings, and provide substantial remedial powers.

3.3.4. Policy Framework

Since its inception in 2002, the Commission's strategic focus on better regulation has stressed the application of good governance principles and regulatory management tools to all phases of the policy cycle, including decisions implementing secondary legislation. In view of this, the Commission policy framework for the implementation of laws is integral to the 2015 Better Regulation strategy, updated in 2017.[18]

18 See: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en.

This is an important governance mechanism. It provides a comprehensive framework for the potential application of good regulatory practices to implementing processes and mechanisms. Indeed, the inclusion of significant comitology measures within the scope of the Better Regulation guidelines is stated explicitly, and a number of proposals have been made subject to ex ante impact assessments. Proposed comitology measures should also be subject to a minimum four-week consultation period. Alongside these requirements, a number of the technical "toolkits" provided to regulators as part of the Better Regulation policy provide important guidance that is relevant for assessing some of the specific issues created by implementing measures. These include identifying risk-risk trade-offs and understanding dynamic regulatory impacts, including the potential for "defensive R&D".

The Commission's Better Regulation policy is an important, yet largely under-exploited, potential mechanism for governing the EU Administrative State. It remains, however, focused on secondary legislation rather than implementing measures. Indeed, it is trapped conceptually in a model of EU law-making that devolves implementation to Member States, rather than recognising the emergence of a powerful and extensive EU Administrative State. There are, moreover, major gaps in the coverage of the Better Regulation policy that limit its potential to strengthen the governance of the EU Administrative State, as laid out in the following points.

- **There are gaps in the political commitments and principles set out in the most recent update of the strategy.** It fails, for example, to explicitly require risk management interventions to ensure health, safety and the environment whilst at the same time promoting innovation; to be based on evidence; to demonstrate that benefits justify costs; to ensure that net risks are reduced; and to seek the least restrictive measure.

- **Better Regulation requirements do not apply directly to decision-making processes that are internal to EU agencies (and decisions by those bodies) or to scientific assessments or to substantive guidance.**

- **The minimum period of consultation for proposed comitology measures is too short.** This is a particular problem when a measure is subject to an impact assessment.

- **There is a lack of emphasis, within the guidelines underpinning ex post evaluation, on the importance of identifying the negative and positive "horizontal" impacts of implementing measures.** Such impacts are observable from the evaluation of various policy areas and sectoral interventions. Horizontal impacts generated by risk management measures include increased defensive R&D and higher capitalised development costs, value chain distortions, reduced operating efficiency, less substance availability, stigmatisation, and risk-risk trade-offs.

- **Technical toolkits fail to cover some of the most important negative regulatory impacts of implementing measures**, most notably the impact of restrictions on the availability of upstream technologies (or innovation) on downstream value chains. There is also failure to include adequate guidance to enable regulators to avoid policy inconsistencies, regulatory overlap, or disproportionate risk management measures.

- **Standards for scientific integrity, and hence the quality of studies, assessments, communication, and experts, are not included within the Better Regulation guidelines.**

3.3.5. Institutional Architecture

In 2015, the Commission established the Regulatory Scrutiny Board (RSB). This is an independent institution that reviews the quality of impact assessment that support proposed interventions, including, increasingly, implementation decisions made using the comitology processes. As part of the process of oversight, the RSB has developed significant competencies and its work is widely respected. It is an important mechanism, if fully exploited, for strengthening the governance of the EU Administrative State.

Whilst recognising the central role of the RSB, it is important to note that there continues to be important gaps in the institutional architecture needed to ensure good governance of the EU Administrative State. These specific gaps are listed below.

- **There is no central institution clearly responsible for resolving problems of regulatory overlap or for determining the criteria for resolving such**

conflicts. Overlaps, where multiple laws regulate the same risks, are endemic within mature regulatory frameworks. Their presence creates uncertainty and, in certain instances, can significantly erode operating efficiency or incentives to innovate. In practice, inter-service dialogue within the Commission has proven to be an inadequate mechanism for resolving these problems. Ideally, an impartial central institution should operate so as to resolve regulatory overlaps with a presumption for the retention of accumulated wisdom, stability, and limiting negative unintended consequences.

- **There are no organisational or procedural arrangements for the development, implementation, and enforcement of the common principles and guidelines needed to protect scientific integrity.** As a result, scientific assessments, the bedrock on which decisions to implement risk management laws rest, are not systematically of the highest quality.

4. Nature of the EU Administrative State

Implementation of risk management measures through the EU Administrative State takes place using a two-stage process:

- **Assessment of Evidence and Preparation of Draft Measures** – in the first stage of the process, a number of different institutional actors and procedures are coordinated by the European Commission to assess available evidence, principally science, and to prepare proposed risk management measures (Section 4.1.).

- **Implementation of Measures** – three principal EU Administrative State mechanisms are used to implement draft risk management measures: standards; comitology (Section 4.3.); and substantive guidance (Section 4.4.).

4.1. Assessment of Evidence and Preparation of Measures

4.1.1. Characteristics

Unlike many other governments in the OECD area, there is no common model for the assessment of evidence and preparation of draft measures by the EU Administrative State. Risk management laws, passed to mitigate different threats and in response to different concerns, prescribe specific but not uniform approaches. Development has been piecemeal leading to a range of different processes and bodies undertaking assessments and preparing draft risk management measures. These include:

- Decentralised risk assessment agencies – ECHA, EMA, and EFSA;
- Independent Scientific Committees overseen by DG SANTE;
- Technical Working Groups composed of Member State experts;
- National Member State authorities;
- National scientific expert organisations;
- External experts; and,
- Commission Services.

In such a heterogeneous context, an obvious problem for regulators seeking to control the quality of implementation measures is the difficulty of imposing common regulatory process standards. It makes it difficult, for example, to ensure that assessments are conducted in a timely, transparent, and predictable manner, and that proposed measures are proportionate, recognise costs and benefits, and ensure that net risk is reduced.

The most important form of evidence used for the preparation of risk management measures is normally scientific. This is usually obtained through a scientific assessment (Exhibit 8).

EXHIBIT 8

THE PIVOTAL ROLE OF SCIENTIFIC ASSESSMENTS FOR IMPLEMENTATION OF RISK MANAGEMENT

Scientific assessments are evaluations of a body of scientific or technical knowledge that typically synthesises multiple factual inputs, data, models, assumptions and/or best professional judgements to bridge uncertainties in the available information. These assessments include, but are not limited to state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterisations of substances; integrated assessment models; hazard determinations; or exposure assessments.

Indeed when making decisions about the best way to manage risks to human health, public safety, and the environment, scientific evidence provides decision-makers with unique insights.

Used well, scientific evidence enables regulators to identify the existence of hazards and their causes; determine which hazards pose the greatest risks to man or nature; reduce uncertainties, characterise risks; identify the existence of new, unintended risks from government action (risk-risk); and identify the benefits of government action. Low-quality scientific assessments are one of the most common ways in which the EU Administrative State fails to implement laws effectively.

4.1.2. Strengths

Evidence from ERF research undertaken over the last decade suggests that, when implementing risk management laws, high-quality assessment and preparation processes and institutions have a number of distinct characteristics. These include the institutional setting, the preparatory procedures, and the scientific assessment underpinning draft risk management measures (Exhibit 9).

EXHIBIT 9

IMPLEMENTATION OF RISK MANAGEMENT LAWS CHARACTERISTICS OF HIGH-QUALITY ASSESSMENT AND PREPARATION

1. **Scientific assessments, the most important source of evidence for the management of risk, are impartial and excellent.** To achieve these standards, assessments are undertaken by eminent, relevant experts. Their findings are based solely on credible, relevant, and high-quality scientific knowledge. Assessment of evidence uses accepted theories that respect accumulated wisdom, the scientific method, and reflects the weight of evidence. Use of the Precautionary Principle is avoided at this stage. Important assessments are subject to independent peer review. And, scientific integrity is respected by adherence to agreed principles and guidelines.

2. **Approval and licensing processes are speedy, predictable, and globally respected.** To meet these requirements, processes are science-based and undertaken by relevant, eminent experts. Testing and compliance requirements are stable and effective. They are known and agreed in advance, based on credible scientific evidence, legal requirements, and real-world experience, and demonstrate measurable improvements in protection. Duplication of testing is avoided. And, timeliness and test requirements are benchmarked against relevant global peers.

3. **Draft risk management measures avoid regulatory failure.** This occurs when measures are proportionate; based on credible evidence; properly informed through consultation and scientific hearings, reduce net risk, and take account of a rigorous understanding of costs and benefits, including value chain and other dynamic impacts.

4. **Procedural rights are protected.** To achieve this, affected parties have rights to redress using independent administrative appeals procedures that consider substantive and procedural concerns, including failings of scientific assessments, and possess significant remedial powers.

Over the last twenty years, the EU institutions have taken steps to meet these standards. New institutions have been established; a number of existing assessment and preparation processes have been reformed; and good practices have been encouraged in a number of different areas with some examples below.

- Creation of independent scientific committees supporting DG SANTE – this is a significant institutional reform that provides expert advice in defined areas and establishes standards of excellence and independence that are intended to apply to all providers of scientific advice to Commission Services.

- Establishment of three decentralised risk assessment agencies (EMA, EFSA, and ECHA) – these institutions functionally separate assessment and management of risk; expand assessment capacity; strengthen expertise; and, champion science-based decision-making. At their best, they also enhance transparency, deliver globally-respected and harmonised decisions, and, speed up access to the Single Market.

- High-quality, speedy and predictable product approvals delivered by EMA for many human medicines – these are globally-respected; undertaken by expert sub-groups; informed by scientific hearings and regular dialogue with applicants; and based on stable test requirements agreed in pre-submission discussions. Approval times are consistent with global peers.

- Revisions of product approval processes used for veterinary medicines and novel foods to strengthen the use of centralised institutions thereby speeding up decision-making, as well as improving consistency and reducing unpredictability.

- Removal of requirements for formal renewal of marketing licences for existing animal health products.

- Adoption of an internal board of appeal by ECHA.

- Use of specialist expert panels for scientific assessments by EFSA.

- Use of peer review by EMA to ensure the quality of scientific assessments of new human and veterinary medicines.

- Rules of Procedure adopted by DG SANTE's independent scientific committees.

- EU-ANSA network of regulatory scientists in EU agencies.

- Use of ex post evaluation tools to assess the efficiency and effectiveness of some product approval processes.

All of these initiatives and examples demonstrate the potential within the EU institutions for adopting best practice and for achieving excellence.

4.1.3. Weaknesses

Despite these improvements, there is a clear lack of consistency in the quality of the performance of the EU's institutions and processes used to assess risks and prepare risk management measures.

In too many cases, approval processes are slow or unpredictable; standards of scientific integrity are not adequately respected; proposed risk management measures are poorly informed or disproportionate; and procedural rights are insufficiently protected. Standards set by global peers are not matched on a systemic basis (Exhibit 10).

EXHIBIT 10

ASSESSMENT OF EVIDENCE AND PREPARATION OF DRAFT EU IMPLEMENTATION MEASURES: MAIN PROBLEMS

- Extended testing costs and time for product approvals
- Unjustified delays in assessment and approval of test dossiers
- Lack of predictability of approval decisions
- Disproportionate risk management measures
- Failure to consider complex unintended consequences of risk management opinions
- Undue influence of old or low-quality or unscientific evidence in scientific assessments
- Inappropriate application of the Precautionary Principles within scientific assessments
- Failure to ensure that eminent, relevant experts undertake scientific assessments

Specifically, the problems involved are listed hereafter.

- **Extended testing costs and times for product approvals** – for many new and existing substances and products mandatory tests are required to demonstrate safety, and, on some occasions, quality and efficacy too. After testing is complete, data is submitted to the EU Administrative State for assessment and approval.

  Compared to global peers, EU requirements in a significant number of risk domains increase the time, cost, and uncertainty of the testing process without any demonstrable improvement in protection. These problems are the result of a number of factors, including: unclear requirements, because of the need to comply with draft guidance; changes in requirements during the testing process; additional requirements applied retrospectively during the testing process; lack of pre-submission hearings; application of requirements that lack robust scientific justification based on risk and relevant, real-world exposures; additional EU-specific requirements that fail to demonstrate any

reduction in risk; and, a failure to accept studies carried out in other parts of the world to globally accepted standards.

- **Unjustified delays in assessment and approval of test dossiers** – after testing is complete, the EU Administrative State uses a range of different institutions and processes to assess dossiers and to determine whether or not to approve a new product or to renew the licence to market an existing one.

Across a wide range of risk domains, the EU undertakes this process of assessment and approval unjustifiably slowly and, all too often, the time required is significantly in excess of that required by global peers to undertake similar reviews (Exhibit 11).

EXHIBIT 11

UNJUSTIFIED DELAYS IN APPROVALS – EXAMPLES

Approval of an importation licence for a GM crop into the EU takes, on average, at least 60 months compared to 18 months in the USA, Canada, and Brazil. Approval for a new crop protection product takes more than 48 months in the EU, compared to 30 months for the USA, Canada, and Australia.

Prior to recent reforms, it was estimated that the average time needed to approve a new novel food for consumption in the EU was at least 48 months, compared to less than 6 months in the USA.

Even without considering global comparisons, it is evident that EU product approval processes lack timeliness. Approval of continued use of a biocide takes almost 36 months, for example, whilst approvals of food contact materials require 16 months, and food nutrition decisions take on average 21 months.

Such lengthy delays have significant consequences. They increase capitalised development costs, preventing investments from recovering the cost of capital and thereby deterring future investment in the EU. They also delay the availability for the EU, its citizens and businesses of new and improved ideas. Over time, this erodes incentives to innovate and hampers ways to improve further protection of human health, animals, and the natural world.

These problems are caused by a number of issues, including a lack of technical and scientific capacity; retrospective application of new or revised or draft test requirements during the approval process; lack of scientific expertise; undue focus on scientific curiosity or hypothetical exposures rather than real-world risks; failure to ensure impartiality of all scientific experts; inadequate coordination between Member States; and, competing interpretations amongst Member States.

- **Lack of predictability of approval decisions** – high-quality approval processes generate decisions that, based on the scientific quality of the data submitted and the extent of compliance with test and other requirements, are predictable. It is assumed that similarly qualified scientific experts will reach the same decision.

  All too often, however, approval decisions made through the EU Administrative State are not predictable. Products or substances are not approved, despite satisfying explicit test requirements; additional usage restrictions are recommended without robust scientific justification; or, additional studies are required that fail to demonstrate improvements in protection.

  There are a number of reasons why approval decisions sometimes lack predictability. These include: inappropriate application of the Precautionary Principle; a risk management strategy, within the risk assessment phase; lack of technical and scientific expertise; and, undue influence of political or ideological conflicts of interest.

- **Disproportionate risk management measures** – at the end of the process of assessing risks, the EU Administrative State generates risk management opinions. These are draft measures designed to reduce risk. To avoid regulatory failure, these should be proportionate to the risk to be managed. All too often, however, this is not the case.

  There are a number of problems: measures fail to address the target risk directly or indirectly; proposed measures fail to demonstrate an adequate assessment of the scale and nature of the risk to be managed, and of the regulatory costs of the proposed measure, including benefits foregone, dynamic impacts, and changes in net risk; least restrictive options are insufficiently considered; and no credible cost effectiveness relationship is demonstrated.

Disproportionate risk management opinions are caused by a number of factors, including: a lack of scientific rationale based on real world exposures and practicability; failure to ensure that measures are achievable and measurable; lack of understanding of the full range of potential costs of risk management opinions, such as value chain impacts, increased net risk, and weakening of incentives to innovate; usage restrictions or exposure limits or other measures not fully informed by scientific evidence and real-world exposures; and the lack of formal requirements for implementation measures to demonstrate that least restrictive approaches have been used and that benefits justify costs.

- **Failure to consider complex, unintended consequences of risk management opinions** – global good practice suggests that high-quality risk management measures take into account potential unintended consequences, thereby limiting the likelihood of regulatory failure.

  Risk management opinions generated through the EU Administrative State do not always demonstrate that the potential consequences of proposals for citizens, nature, and businesses have been fully considered, and hence are reflected in the design of proposed measures. As a result, proposed measures are unable to demonstrate that benefits justify costs.

  There are a number of reasons for this: lack of understanding of the potential for risk-risk trade-offs; usage restrictions or exposure limits or other measures not adequately informed by scientific evidence or real-world exposures; lack of understanding of complex, dynamic regulatory impacts, including product market distortions, value chain disruption, and diminution of incentives to innovate; and, weaknesses and gaps in the scope of the Commission's Better Regulation policy and guidelines.

  There is also a conceptual misunderstanding of the nature of implementation measures amongst policy-makers. These are not simply technocratic measures put in place by an impartial, expert administration following a series of pre-determined steps with little flexibility. They are regulatory decisions that involve choices about how to manage risks, and hence require an informed understanding of intervention logic, regulatory choices, costs, and benefits.

- **Undue influence of old or low-quality or unscientific evidence in scientific assessments** – most EU risk management legislation requires companies to demonstrate the safety (and sometimes efficacy and quality too) of new and existing technologies using internationally recognised standards. In some instances they also require scientific assessments to consider all known studies. Good practice suggests that this provision should not, however, require poor quality studies or other inappropriate forms of evidence to influence the final outcome of an assessment, rather that there should be a rational and scientific process for considering and, where appropriate, excluding such studies and forms of evidence.

  Final scientific assessments by the EU's scientific advisory processes, however, are not always based solely on scientific studies or evidence that meets accepted standards of quality. In a number of cases the outcomes of scientific assessments appear to have been shaped by studies that no longer reflect scientific knowledge or are inappropriately interpreted or do not meet the standards of the scientific method. As a result of this, there have been, on too many occasions, inconsistencies in evidential standards, leading to poor quality scientific assessments (Exhibit 12).

EXHIBIT 12
LOW-QUALITY SCIENTIFIC STUDIES – SOME CHARACTERISTICS

- Out-of-date studies that fail to reflect modern scientific understanding or have been discredited or even retracted
- Experimental, investigative studies that do not form part of the body of scientific knowledge
- Untested theories of harm
- Novel hypotheses
- Inappropriate or irrelevant exposure methodologies
- Environmental impact models without publicly available data or assumptions
- Weak epidemiological studies that fail to meet well-established standards of quality and utility
- Failure to identify questionable research practices (such as citation bias)
- Inaccurate statistical analysis
- Failures to differentiate adequately between correlation and causation
- Hypothesis-forming assumptions without robust scientific justification

- **Inappropriate application of the Precautionary Principle within scientific assessments** – EU institutions recognise formally that the Precautionary Principle should only be applied during the risk management phase of the overall process of risk analysis. It should not be used within the process of assessing risk.[19]

Scientific assessments undertaken at EU level do not always demonstrate that this requirement is respected fully. Instead, there is evidence of inappropriate application of the concept of systematic precaution, unjustified by long-established approaches of toxicology, within the process of scientific assessment (Exhibit 13).

EXHIBIT 13

INAPPROPRIATE APPLICATION OF THE PRECAUTIONARY PRINCIPLE WITHIN SCIENTIFIC ASSESSMENTS

EXAMPLES

- "Cherry picking" data or studies that support precautionary action
- Unscientific reliance on poor quality studies
- Failure to ensure that scientific assessments are based on the weight-of-evidence derived from modern systematic evidence review
- Failure to rank studies, using internationally accepted standards, on the basis of quality and relevance
- Failure to exclude low-quality studies
- Unjustified use of worst case and hypothetical exposures
- Exclusion of high-quality "nil effect" studies
- Drawing conclusions based on single studies or "outliers"
- Hidden precautionary defaults or assumptions, such as no threshold exposure or read across assumptions employed without credible scientific justification
- Reliance on models and academic studies unrelated to real-world experience
- Application of excessively conservative defaults and other bridging assumptions not justified by scientific evidence

19 European Commission "Communication from the Commission on the Precautionary Principle" (2000, COM (2000)1).

- **Failure to ensure that eminent, relevant experts undertake scientific assessments** – good practice requires that scientific assessments are undertaken within the framework of the EU Administrative State by the most eminent and relevant experts and that all conflicts of interest, including personal, values and financial, be considered when experts are appointed.

  The standards are not always met when the EU Administrative State undertakes scientific assessments. Eminent academic scientists with detailed knowledge of relevant risks may be excluded on the basis of partial conflict-of-interest strategies with the result that expertise within some Technical Working Groups and Scientific Committees may sometimes be inadequate; in contrast, scientists with predetermined views, influenced by ideals, political factors, or ideologies may participate in assessments, and generalist working groups, lacking relevant and detailed knowledge, may undertake scientific assessments of specialist substances or products.

  These problems are the result of a number of factors, including the way in which conflict-of-interest rules are applied by the Commission and its agencies; the lack of modern guidance for managing bias and the complex range of conflicts of interest that cause it; inequalities of scientific knowledge between Member States; failure to appoint eminent experts; pursuit of national political goals rather than assessment of scientific evidence; appointments on the basis of criteria other than excellence; ad hominem criticisms of independent scientists; and a failure of policy-makers to understand how knowledge is generated in modern economies.

Alongside these failings, there are a series of governance weaknesses that erode the quality of the performance of the EU's processes and institutions used to assess risk and prepare risk management measures. Procedural rights are not easily protected because of major gaps in the provision and powers of administrative appeals procedures. Involvement of affected parties is unduly limited because of the inadequate provision of scientific hearings to inform scientific assessments and approvals. And, there is a lack of institutional responsibility for identifying and resolving regulatory overlaps, whereby multiple risk management laws regulate the same risk.

4.2. Implementing Mechanisms – General

The EU Administrative State uses three principal mechanisms to implement draft risk management measures: standards; comitology; and substantive guidance.

- **Standards** – risks posed by a number of technologies, particularly electrical, electronic, and mechanical, are managed using the "new approach", whereby companies are responsible for assessing and managing risks posed by their products. Secondary legislation sets out essential safety requirements, typically reflecting desired outcomes rather than mandating specific technical solutions. Adherence to product-specific technical standards, set by voluntary EU-level standard-setting bodies, provides a means of demonstrating compliance with essential requirements. Historically, standards have been primarily technical in nature, reflecting the risk reduction goals set out in legislation. Introduction of newer standards that reflect social preferences has, however, increased the possibility of informal rules or adjudications that stigmatise particular products.[20]

- **Comitology** – this is the traditional mechanism for providing legally-binding implementation measures and has been expanded to encompass the large number of formal adjudication decisions needed to implement new, ambitious, wide-ranging risk management laws. In some instances, comitology is also used to make substantive guidance legally-binding (Exhibit 14).

- **Substantive Guidance** – derived through administrative processes, substantive guidance is a form of soft law and a source of hidden law-making. These non-binding decisions are made by the executive function when implementing complex legislation (Exhibit 15).

20 This ERF Monograph does not examine the use of standards as an implementing mechanism. It is listed in this section for completeness only.

EXHIBIT 14

THE EU 'COMITOLOGY' SYSTEM

With its origins in the 1960s, comitology provides a means for the Member States, and in some instances the European Parliament, to oversee the use of implementing powers by the Commission. It provided a means of rapidly developing large numbers of legally-binding implementation measures, whilst maintaining the political support of the Member States. The progressive expansion of this highly effective law-making mechanism led to its progressive formalisation and reform through a series of Council Decisions, beginning in 1987, and ultimately the Lisbon Treaty.

Conceptually, the term "comitology" describes the use of formal committees, comprised of Member State representatives, to oversee the use by the European Commission of its implementing powers. Whilst the Commission is responsible for the preparation of measures, Member State experts provide support during this stage, as well as approving draft measures through a network of Standing Committees. Some forms of comitology also require final scrutiny of measures by the European Parliament and Council. Articles 290 and 291 of the Treaty set out the main forms of comitology, although the older "regulatory procedure with scrutiny" remains in use for some risk domains.

At present, Articles 290 and 291 of the Treaty set out the main forms of comitology, although the older "regulatory procedure with scrutiny" remains in use for some risk domains.

EXHIBIT 15

SUBSTANTIVE GUIDANCE IN THE EU

Substantive guidance issued by EU risk assessment agencies, Technical Working Groups and Commission Services is one of the most important mechanisms used to implement risk management laws.

A form of soft law, these non-binding decisions are made by the executive function when implementing complex legislation. They define technical, scientific or regulatory rules needed to comply with statutory obligations. Substantive guidance also includes detailed interpretations of statutory rules by officials. They tend to have general applicability and to apply in the future. For most businesses affected by substantive guidance, it provides, in practice, a detailed definition of the legal requirement. Failure to adhere to substantive guidance is, all too often, seen to be prima facie evidence of non-compliance with the law.

Substantive guidance is also a form of risk management. Detailed safety, quality, efficacy or usage requirements, required to demonstrate compliance or to meet implied safety standards, embed assumptions about the social acceptance of risk, for example. Examples of substantive guidance used to manage risks include the specific test requirements needed to demonstrate the safety, quality, and efficacy of new drugs for humans or animals set out by EMA; documents describing acceptable technologies for managing emissions, workplace exposures and limit values; the extensive requirements needed to implement REACH and hence manage risks posed by the use of chemical substances; and safety testing requirements in areas such as novel foods, food additives, biocides, crop protection, cosmetics, advanced medical devices, and biotechnology.

All too often, substantive guidance is overlooked as a regulatory mechanism for law-making and hence for implementing risk management laws. It is, however, one of the most important ways in which regulatory decisions affect incentives to innovate or the level of net risk.

4.3. Implementation Mechanism – Comitology

4.3.1. Strengths

Comitology continues to grow in importance as a mechanism for implementing risk management laws. It has delivered a number of important benefits. These include:

- Adopting into law large numbers of complex, technical adjudications quickly;
- Facilitating rapid adaptation to technological and scientific change;
- Easing access to the Single Market for substances and products;
- Maintaining political support and commitment amongst Member States; and,
- Strengthening governance of the EU Administrative State by involving legislators in approval and scrutiny of implementing measures.

The EU institutions have recognised its importance as a form of law-making. Significant comitology decisions fall within the scope of the Commission's Better Regulation policy and guidelines. Transparency of the comitology process has been improved through the introduction of the Comitology Register and other similar measures. Finally, the Inter-Institutional Agreement on Law-making focuses on the different comitology processes and when they should be used, seeking to improve predictability.

4.3.2. Weaknesses

Despite these improvements, there remain important structural weaknesses in the comitology processes used to implement risk management laws. Specific problems include:

- **Continued barriers to meaningful input by the public in decision-making processes,** including inadequate public notice of consultation opportunities, and web-based commenting procedures that limit the length and detail of comments;

- **Absence of formal "public dockets"** where all of the information relied upon by decision-makers is collected and is available for public review;

- **Ability of decision-makers to rely on information that is not made available to the public** and hence is not subject to public review and comment;

- **Ability of decision-makers to rely on input from "experts" whose appointment is not subject to defined standards or review**, and whose input is often not subject to formal public review and comment;

- **Limited obligation by decision-makers to explain the legal and factual bases of their decisions**, including responding to comments made by the public;

- **Significant constraints on the ability of EU Courts to meaningfully review such decisions because there is no clearly defined factual or technical record** upon which the public has had an opportunity to comment and on which decision-makers have relied;

- **Unpredictable and inconsistent outcomes** from an opaque process that lacks transparent evidential standards and where decision-making may be influenced by national considerations, leading to "politicisation" of risk management;

- **Differences in scientific or technical expertise amongst Member States** making it difficult for some experts to contribute fully to debates and facilitating "political capture" by other, better informed national experts;

- **Reinterpretation of secondary legislation circumventing the legislative process**, expansion of requirements, inappropriate use of precaution and hazard rather than risk to make decisions, addition of testing requirements or usage restrictions not in accordance with legislation, use of legal bases for new or novel purposes not explicitly envisaged by the EU legislators, and revision of legislation.

4.4. Implementation Mechanism – Substantive Guidance

4.4.1. Strengths

Substantive guidance provides regulators with a critical mechanism for structuring the way in which a wide range of risks are assessed and for delivering risk management outcomes. As such, it helps regulators reduce, shift, or remove potential harms on a systematic or case-by-case basis. In the risk assessment phase, it is used to define hazards, exposures, risks, and levels of acceptable use or exposure, as well as to describe test requirements, methods, processes, and standards needed to demonstrate safety and quality. Individual guidelines include judgements that limit or prevent exposures through decisions about safety limits or test methods or methods of interpreting test data (such as requirements to use worst case scenarios), for instance. This is a form of risk management. Substantive guidance also provides evidence of compliance with risk management requirements.

Used well, and supported by appropriate regulatory decision-making policies and institutions, substantive guidance is a highly effective mechanism for managing risks, creating major benefits for citizens and businesses. Specifically, high-quality substantive guidance:

- Provides regulatory certainty for smaller enterprises, creating legitimate expectations, and defining clearly what must be done to comply with the law;
- Facilitates the implementation of highly complex, poorly drafted, ambitious risk management laws;
- Restricts "administrative discretion" and politicisation amongst regulators, limiting inconsistency of interpretation, and improving the predictability of decision-making;
- Enables regulators to respond flexibly to advances in scientific and technical knowledge by taking timely action to protect the public interest without, in many cases, waiting for new or additional primary legislation;
- Strengthens the evidence-based approach to decision-making, enhancing transparency, effectiveness, and public trust; and,

- Provides a flexible alternative to new technology-specific risk management laws by providing an interpretation of new hazards within the framework of existing laws.

The role of substantive guidance in the implementation of risk management laws is, however, little understood. Reform efforts reflect this. The most notable improvement is the adoption by EMA of formal requirements setting out the process that must be followed when new substantive guidance is required. A concept paper outlines the intervention logic. This is then followed by consultation with affected parties, the development of options, assessment of costs and benefits, further consultation, and, finally, publication of the finalised document.

4.4.2. Weaknesses

Whilst substantive guidance is, at its best, a powerful mechanism for ensuring high-quality implementation, its use in the framework of the EU Administrative State reveals important weaknesses. Quality varies; regulatory impacts are largely overlooked or not understood; it is too often used to embed the Precautionary Principle into risk assessment; and it provides a means to revise secondary legislation without involvement of legislators. Some of the specific problems of this are detailed below.

- **Inappropriate application of the Precautionary Principle within risk assessment** – methods of assessing scientific data and evidence are frequently set out in substantive guidance. In some cases, the Precautionary Principle unduly influences the requirements, assumptions and defaults set out in substantive guidance (Exhibit 16).

- **Revision of secondary legislation without involvement of legislators** – substantive guidance is not always used to develop implementation requirements in accordance with existing laws. On some occasions, it is used to expand the scope of laws, to make them more onerous, stringent, or precautionary, or to impose additional requirements.

EXHIBIT 16

SUBSTANTIVE GUIDANCE, PRECAUTION, AND RISK ASSESSMENT

- Requirements to use worst case scenarios, single studies, outliers, or all studies regardless of quality;
- Dose-response defaults that assume, without scientific justification, no safe level of exposure;
- "Read across" requirements not based on scientific evidence or international standards;
- Requirements to consider hypothetical exposures; and,
- Acceptance of novel, untested theories of harm to justify risk management measures.

- Lack of understanding of regulatory impacts – there is no common, high-quality process for developing or revising substantive guidance. Its importance and impact is not widely understood. On some occasions, this contributes to the development of low-quality measures. Substantive guidance has major regulatory impacts including stigmatisation, defensive R&D, capitalised development costs, restrictions on usage, higher operating costs, capital expenditure, value chain distortions, and restricted technology utilisation.

- Frequent revisions and additions without robust, relevant scientific justification – good practice suggests that substantive guidance requirements should be stable. This facilitates certainty and reduces regulatory costs, such as unpredictability and diversion of resources. On too many occasions, substantive guidance frameworks developed within the EU Administrative State are revised or expanded without a clear justification grounded in relevant scientific evidence or established advances in knowledge or demonstrable improvements in risk reduction.

- Variable quality of substantive guidance – a significant part of the substantive framework used to implement risk management laws is of good quality. In some instances, however, substantive guidance is disproportionate, unnecessary, based on academic curiosity not risk reduction, or poorly designed and drafted. A cause of this is the lack of a common process, based on the principles of the Commission's Better Regulation policy, for developing substantive guidance. With the notable exception of EMA, there is a lack of

a requirement to demonstrate the intervention logic, to develop least onerous options, or to consider costs and benefits. These weaknesses may be further exacerbated by gaps in relevant expertise in some parts of the EU Administrative State.

Shortcomings in governance amplify the impact of these weaknesses (Exhibit 17).

EXHIBIT 17
SUBSTANTIVE GUIDANCE – UNDERLYING GOVERNANCE SHORTCOMINGS

Underlying the problems set out above are two additional governance weaknesses:

- First, substantive guidance does not fall within the scope of the Commission's Better Regulation policy. This omission makes it difficult for a common approach to the development or revision of substantive guidance to evolve.
- The second problem is also a failing of governance. Because it is a form of soft law, lawyers have found it difficult to bring substantive guidance within the scope of judicial review, thereby limiting the enforcement of due process standards and of procedural rights of affected parties.

5. Regulatory Impacts

5.1. Benefits

Citizens, the EU institutions and businesses benefit from a well-governed EU Administrative State that makes high-quality implementation decisions.

5.1.1. Citizens

If complex risk management laws are implemented poorly, citizens lose out. Decisions that are not of high quality often fail to deliver societal goals or may generate rules and

adjudications where the cost of regulation exceeds its benefits or there are substantial negative unintended consequences. These shortcomings lead to "regulatory failure", limiting the socio-economic benefits of public policy. Indeed, net risk may be increased rather than reduced.

Poor quality rule-making creates governance failures as well, because the right of citizens to be governed well is not respected. This erodes confidence in government, undermines legitimacy, and generates uncertainty, powerlessness and distrust.

A well-governed Administrative State helps overcome both of these problems by:

- facilitating better decision-making, limiting the extent of "regulatory failure" and hence increasing the socio-economic benefits of public policy (jobs, wealth, security, safety, choice, quality of life); and,

- ensuring better governance.

Improvements in overall EU governance and administration, and in particular in the area of risk management, will ensure that citizens are better protected from potential harms whilst innovation will be encouraged (through greater predictability in R&D investments and enhanced legal certainty). Investments in innovation deliver greater choice, lower costs, new experiences, safer products, improved quality of life and sustainable prosperity.

Over time, good governance of the implementation of laws will help enhance the legitimacy and effectiveness of the European Union's institutions, especially in times of crisis when trust in public authorities is critical.

5.1.2. EU Institutions

The European Union, and its institutions, is facing a crisis of legitimacy. In part this is a consequence of long-term, well-understood governance weaknesses, often described as the "democratic deficit". There are problems of euroscepticism as well.

A well-governed EU Administrative State making high-quality decisions that implement risk management laws provides an opportunity to start tackling these wider problems. It does this in three ways:

- It strengthens the rule of law;
- It delivers high standards of protection without eroding incentives to innovate; and,
- It complements existing reform initiatives within the EU institutions, helping to accelerate other governance changes.

Indeed, the European Commission is committed to delivering improvements in governance and economic competitiveness, in part through implementation of its "Better Regulation" strategy. Over the last decade, this approach has delivered major improvements in regulatory management.

5.1.3. Business

On too many occasions the implementation of complex risk management rules at EU Level has created significant problems for businesses, triggering adverse impacts for Europe and its citizens.

Politicisation of decision-making, slow and high-cost regulatory processes, opacity, disproportionate or unjustified use of precaution, administrative discretion and "regulatory capture" by interest groups erodes the quality of rule-making and adjudications, making implementation unpredictable, and creating risk aversion. Taken together, these characteristics of the EU's approach to implementing risk management laws limit returns from existing investments, undermine incentives to innovate, and weaken the attractiveness of the EU as a location for investment.

High-quality implementation decisions reduce these problems significantly. Specifically, businesses benefit from high-quality decision-making by the EU Administrative State in five ways as laid out below.

- **Better quality rules and adjudications** – these reduce the unjustified loss of well-established products and markets and limit stigmatisation, protect existing investments, demand and margins. Downstream businesses in complex value chains also benefit because a greater availability of materials provides more opportunities for incremental innovation.

- **Increased certainty** – this reduces the capitalised cost of investments in innovation and enhances projected returns from existing assets, making Europe more attractive for capital allocation decisions.

- **Greater proportionality** – this highlights benefit-risk trade-offs, strengthens social acceptance of risk, creates powerful incentives to invest in innovation, and promotes the use of precaution in accordance with the criteria set out by the European Commission.

- **More favourable market conditions** – market opportunities are stronger when good quality risk management decisions build consumer confidence in the safety and performance of products and facilitate rapid access to the EU Single Market, as well as, ideally, providing a "gold standard" of product approval that opens up opportunities in non-EU markets.

- **Lower regulatory costs** – expenditures needed to meet standards and to demonstrate safety, quality or efficacy are more rational, evidence-based and derived from well-accepted science, leading to lower capitalised costs for innovation decisions, less "defensive R&D", and greater retention of safe, well-established substances and technologies.

Over time, such improvements in the impact of regulatory decision-making on businesses make the EU a more attractive location for investment, innovation, and risk-taking.

5.2. Problems

5.2.1. Implementation Decisions and Competitiveness

EU risk management laws, and the decisions that implement them, seek to protect human health, public safety, and the environment. At the same time, they have a powerful impact

on the competitiveness of businesses and, hence, their capability to meet the demands of society for jobs, prosperity, choice, and new ideas. In turn, this affects sustainability, and safety. The vast scope of implementation decisions affects competitiveness in a number of different ways. The challenge facing regulators is to minimise the negative socio-economic consequences of risk management decisions whilst, at the same time, delivering a high standard of protection.

In particular, regulators must recognise that:

- Slow, costly, and unpredictable product approval and re-licensing decisions affect the availability of resources for innovation, investment economics, and substance/product availability.

- Decisions based exclusively on hazard classifications directly affect operating expenditures, capital requirements, production costs, and waste, as well as triggering restrictions, eroding existing returns, limiting future innovation, and influencing downstream usage of substances.

- Decisions to place substances or products on public blacklists trigger stigmatisation, expressing official concern for safety, distorting product markets, and triggering changes in usage, revenues, and margins.

- Poorly informed decisions restricting usage of materials or technologies pose problems for the creation of prosperity and jobs throughout complex value chains. Moreover, they erode retained earnings from existing investments, and promote the use of substitutes that may increase net risk.

- Disproportionate limits on exposures or emissions increase the cost of operating facilities in Europe, reduce returns from existing investments, and, hence, diminish the sustainability of assets.

5.2.2. Regulatory Weaknesses

Whilst a significant proportion of the decisions taken through the EU Administrative State to implement risk management laws are of high quality,

too many have a negative impact on competitiveness. This is caused by major regulatory weaknesses, as outlined below.

- **Time** – product approval processes for new and existing products, including the time needed to carry out testing, is excessively lengthy for certain products, technologies, and substances.

- **Cost** – costs of carrying out tests to demonstrate safety, and other characteristics of new and existing products are excessively high in certain cases.

- **Precaution** – for some products, technologies, and substances, implementation measures are unduly influenced by precaution, including its utilisation within the process of scientific assessment.

- **Proportionality** – too many risk management measures are disproportionate. Risks are not targeted directly; measures are unduly restrictive; there is an inappropriate balance between regulatory cost and the effectiveness of measures; dynamic regulatory impacts are ignored; and the potential for risk-risk outcomes is insufficiently considered.

- **Uncertainty** – for some products, technologies, and substances implementation outcomes are uncertain and unpredictable. Additional restrictions are imposed; approvals or licences are refused; further testing is demanded; and requirements are made more precautionary. Some decisions are politicised, whilst others depend on administrative discretion or are influenced by a lack of expertise.

5.2.3. Regulatory Outcomes

Decisions that implement risk management laws have complex and extensive positive and negative impacts on the competitiveness of businesses.

Poor quality decisions are characterised by regulatory failings of time, cost, precaution, proportionality, and uncertainty, and, over time, generate a series of negative regulatory outcomes for Europe and its citizens. Some specific problems are outlined below.

- **Risk-risk outcomes** – in a number of instances, the imposition of regulatory requirements has led to an increase in net risk. This has occurred for a number of reasons. Mandatory substitutions or restrictions on usage have led to the use of less safe replacement technologies or products. High costs of complying with safety testing have triggered the removal of existing substances or products creating new risks or reducing mitigation of existing ones. And, the cost of replacement technologies has triggered behavioural change and subsequent increases in risk.

  Examples from the veterinary medicine and biocides sectors illustrate these impacts (Exhibit 18).

EXHIBIT 18
RISK-RISK OUTCOMES

In the case of **veterinary medicines** over 70% of existing products have been withdrawn from the market since 1991 because of the costs of meeting new safety requirements. In most cases they have not been replaced because of the small size of markets and the high level of capitalised costs of product development, due, in part, to regulatory requirements. As a result there is a **medicine availability crisis** for many animal species and gaps in the armoury of products needed to protect against zoonotic diseases.

There is a similar problem with **biocides**: a range of speciality products that are essential to protect human life and property from pathogens. Since the mid-1990s, the number of actives has fallen from 1100 to less than 250, and almost none have been replaced. This loss of actives, particularly when faced with the need to combat biological mutation, poses major risks to human health.

- **Defensive R&D** – Defensive R&D occurs when new regulatory requirements are applied to existing products, substances, or technologies. In turn, this necessitates the use of science and technology budgets to be used to ensure regulatory compliance. Mandatory expenditure to demonstrate the safety or efficacy or quality of existing substances, even when there is no evidence of harms, diverts scarce resources away from investment in new ideas. Companies when faced with this requirement do not,

in general, allocate additional resources to innovation. In the light of this, innovation resources in the EU are used, all too frequently, to prop up old technologies rather than to develop new ones or to support incremental improvements.

A further impact is the loss of access to established technologies by downstream companies within value chains because of regulatory-induced decisions by upstream producers to de-list products thereby avoiding defensive R&D. In many sectors, companies rely on access to a "palette" of proven technologies, many of which are embedded in substances purchased from suppliers. This is particularly the case for SMEs operating in the downstream parts of the EU's value chains.

The experience of the agricultural machinery, veterinary medicine, and biocide sectors illustrates the problem of defensive R&D (Exhibit 19).

EXHIBIT 19
DEFENSIVE R&D

The **agricultural machinery** sector provides a powerful example of this regulatory problem. For more than five years, manufacturers of agricultural machinery were forced to divert 70-80% of R&D to develop engine technologies capable of meeting emissions standards required of passenger vehicles, despite evident differences in risk. Overall expenditure on defensive R&D to achieve this regulatory requirement was more than €10 billion. Capital was diverted away from productive investment in new agronomic technologies; the cost of new vehicles was increased by 25%; and, industry restructuring was triggered. Additional risks were created as well. Older, more polluting vehicles were retained for longer, because of the increased cost of new vehicles, leading to higher rather than lower emissions.

In other sectors, high levels of defensive R&D have helped to restrict technological improvements, locking in old approaches and limiting the attractiveness of the EU as a location for innovation. Between 30-35% of R&D has been spent annually to keep old **veterinary medicine** products on the EU market since 1991. In contrast, veterinary medicine companies in the USA have spent only 15% of R&D annually on defence in the same period.

The situation facing producers of **biocides** in the EU is even more challenging. Almost 100% of annual R&D is spent keeping old products on the EU market, and no new active has been placed on the EU market since 2005.

- **Capitalised development costs** – regulatory factors have a powerful impact on the capitalised costs of developing new products, and hence on the scale of market opportunity needed to recover them. Capitalised costs, that take into account cash outflows, time-to-market, the cost of capital, and uncertainty, must be recovered in full if businesses are to continue to invest in innovation. The greater the scale of expected capitalised cost, the larger the market opportunity required before investment takes place.

  Poor quality implementation decisions taken through the EU Administrative State increase the capitalised cost of product development in the EU for certain products and substances. This occurs because of excessive cost and time needed for testing and product approval, as well as the uncertainty and unpredictability of EU implementation mechanisms. Regulatory-induced increases in development cost in the EU trigger, over time, reduced investment in innovation, delocalisation of R&D activity away from the EU, retention of old technologies, lower product availability and industry restructuring.

  Two detailed examples, one from the crop protection sector and the other from the veterinary medicine sector, highlight this problem (Exhibit 20).

- **Access to technologies** – in large parts of the EU's economy, innovation and the creation of jobs and prosperity takes place through the complex functioning of value chains. Downstream manufacturers and users rely upon the properties of complex materials or investments in innovation provided by upstream producers. These are platform technologies. The effective functioning of these upstream "motors of innovation" is distorted by poor quality implementation of risk management laws.

  A number of regulatory impacts inhibit the potential of downstream value chains to exploit platform technologies provided by upstream suppliers. High levels of defensive R&D reduce the availability of resources for upstream producers to invest in innovations that can be exploited by other parts of their value chains. Actions by upstream producers to reduce regulatory expenditure on existing products leads to the removal of upstream technologies on which downstream users rely to create added value. And, restrictions on the use of upstream materials reduce the scope for downstream users to exploit their unique properties. These issues are, however, little

understood by regulators, and, as a result, are insufficiently considered when the EU Administrative State implements risk management laws.

Two examples, one from the fragrance blend industry and the other from the non-ferrous metal industry, highlight the scale and nature of the impact of upstream platform technologies on downstream value chains (Exhibit 21).

EXHIBIT 20

CAPITALISED DEVELOPMENT COSTS

The cash cost, excluding time-to-market and the cost of capital, of developing a new active for the **crop protection** sector has risen, in real terms, from US$150 million in 1995 to US$290 million in 2017, primarily because of increased safety and environmental testing requirements. Combined with the high regulatory costs of retaining existing actives, this increase in product development costs has contributed to a major reduction in the armoury of crop protection products available to Europe's farmers. Excluding naturals, the number of actives has fallen by 70% in twenty years limiting the availability of substances for certain speciality crops and creating the possibility of negative economic consequences. New advanced substances have not replaced these lost actives. Numbers of new actives approved and commercialised between 2011 and 2018 was approximately one per annum.

Evidence from the **veterinary medicine** industry reveals a similar story. Regulatory requirements increased the time and cost needed to develop a new product for a major livestock and companion animal species. Between 1991 and 2011, time increased by 7.5 years and costs by 229% for a major livestock species because of regulatory factors. The equivalent figures for a companion animal product were 4.0 years and 173% increase in costs due to regulatory factors. Moreover, these increases in capitalised costs have not been reduced subsequently. Such large, long-term changes, combined with the small size of animal health markets, have influenced investment decision-making. There has been a shift away from investing in new, innovative products and towards incremental improvements of existing technologies, and an overall reduction in annual expenditure on R&D in the EU from more than 10% of turnover to less than 8%.

EXHIBIT 21

DOWNSTREAM VALUE CHAINS

The **fragrance blend** industry provides an indication of the potential importance of upstream innovation for the prosperity and competitiveness of downstream users. A small specialist industry with EU turnover of €2.2 billion, the distinctive contributions of fragrance technologies supports Gross Value Added (GVA) of more than €63 billion. Through annual investments in innovation of 15-18% of turnover annually the fragrance blend industry combines artistry, science, and consumer understanding to create unique fragrance combinations that allow the Fine Fragrance, Beauty, Household Care and Personal Care producers to create new products, to improve existing ideas, to differentiate, and to deliver value added.

Non-ferrous metals illustrate a similar relationship between upstream platform technologies and downstream users. The distinctive contribution of nickel technologies, for example, support GVA of more than €50 billion in a complex downstream value chain including alloy producers, metals plating, and manufacturers of gas turbines, medical equipment, jet engines, and specialist equipment for food, chemical, and hydrocarbon production. They are also essential for the performance of modern batteries, and hence have the potential to contribute to the EU's sustainability goals. To achieve this, however, it will be important for implementation decisions, particularly those involving metallic chemicals, to recognise these complex value chain impacts.

- **Business sustainability** – implementation of risk management laws through the EU Administrative State can, in certain circumstances, threaten the sustainability of businesses. Most notably, this occurs when poor quality implementation decisions induce changes in market conditions that reduce demand, margins, returns on capital, and solvency; divert capital spending and increase operating costs due to disproportionate limits on emissions or exposures; increase material input costs because hazard classifications restrict use of waste or recycling; or, increase product development costs that trigger industry restructuring away from new ideas and towards retention of old ones.

The evolution of the agricultural machinery sector, shaped in part by regulatory decisions, highlights this problem (Exhibit 22).

EXHIBIT 22
BUSINESS SUSTAINABILITY

Changes in the market dynamics of the agricultural machinery sector, triggered by requirements to match the emissions performance of passenger cars, illustrate part of this problem. Because of the high cost of achieving these new, disproportionate regulatory goals, market prices for new vehicles rose by 25% and demand fell by 45%. A combination of these market changes, and the damage to solvency caused by the cost of investing in new engine technologies, forced smaller European producers to leave the market (leading to job losses) or to be taken over by Chinese or Indian competitors.

- **Market attractiveness** – risk management decisions can affect the expected returns from current and future investments. This can occur because of increases in the cost of developing new products or operating costs or capital intensity. It can also result from losses of existing contribution margins because of disproportionate or poorly designed restrictions on use or because of stigmatisation due to listing decisions. Poor quality risk management decisions affect perceptions of risk-takers too. They can signal aversion to risk and a lack of support for innovation. Collectively, these problems distort the allocation of capital to the EU, reducing the willingness of investors to support new ideas.

  The limited growth of the agricultural biotechnology sector in Europe provides an example of how these implementation issues, combined with legislative design, has significantly reduced the attractiveness of the EU for investment in radical innovation in a major part of the life science sector.

Taken together, these negative regulatory outcomes pose challenges for the European Union. They reduce incentives to invest in innovation and erode returns from markets and existing investments. This threatens employment and prosperity, and makes it more difficult for Europe's citizens to enjoy the social benefits of risk-taking, such as greater

sustainability, access to new and exciting ideas, lower prices, better care for food producing and companion animals, protection from zoonotic disease or pathogens in the home and at work, and prosperity for farmers of speciality crops. Instead, there is the possibility that the EU will become locked into a declining stock of old technologies unable to achieve its wider social aspirations.

A further challenge is the failure to reduce net risk because of the unintended negative consequences of poor quality implementation decisions. Over time, this is a form of regulatory failure that potentially undermines the central rationale for the involvement of government in the management of risk: its unique capacity to protect people and nature against involuntary risks.

6. Conclusions

One of the most important ways in which the European Union meets the social demands of its citizens is through the management of risks to human health, public safety, and the environment posed by technologies and lifestyle choices. Achieving this is difficult. Risks cannot be mitigated or avoided or a better world created simply by passing secondary legislation. Success depends on making very large numbers of high-quality implementation decisions – primarily adjudications and rule-making – across a wide range of risk domains.

To try and achieve these goals, the EU has, over the past two decades, created an Administrative State, using regulations rather than directives to set out secondary legislation, establishing new, centralised risk assessment institutions, and using soft law and comitology to make implementing decisions. The decisions made by this new, "fourth branch" of government have a powerful impact on the levels of protection enjoyed by citizens and on incentives to innovate.

Steps have been taken by the EU institutions to strengthen the governance of this powerful decision-making branch of the executive function, and to improve the consistency and quality of the implementation decisions it makes. Many of these reforms have been successful and are to be welcomed. Indeed, many of the decisions made through the EU Administrative State to implement risk management laws are of good quality.

Despite this, more needs to be done. In too many cases, decisions are disproportionate or unduly precautionary or unpredictable or take too long and impose unjustified costs. These are major failings. They can lead to an increase in net risk, less investment in innovation, disruption of value chains, erosion of business sustainability, and a fall in the attractiveness of the EU for global investors. Europe's citizens do not benefit from this, and such outcomes undermine the legitimacy of EU institutions.

There are obvious reasons for these failings. Governance exhibits significant failings, such as the lack of an EU Law of Administrative Procedures, inadequate political commitments to governing the Administrative State, and a failure to establish procedural rights. There is, moreover, no common model for the assessment of risk and preparation of risk management measures, making it difficult to achieve consistent, high-quality decision-making. And, policy-makers have not addressed the major structural weaknesses of comitology and substantive guidance that limit their effectiveness as high-quality implementation mechanisms.

Lying behind these explanatory factors are a series of more challenging underlying causes as outlined below.

- **The development of the EU Administrative State has been piecemeal.** There has been no over-arching plan to ensure good governance and high-quality decision-making. Institutions and processes have been established principally in response to the progressive conferral of increased competence at EU level and to specific concerns, rather than being shaped by a model of good government.

- **The design of risk management laws has failed to take into account sufficiently the difficulties of making very large numbers of high-quality implementation decisions.** Problems created by failings of legislative design include mandatory requirements to renew marketing approvals without credible evidence of changes in risk; failure to ensure coherence between risk management laws and other policies; poor quality and ambiguous legislation creating difficulties for implementation; failure to consider regulatory overlap, and how to resolve it; and, lack of detailed examination of implementation processes and mechanisms.

- **The major mismatch between the ambitions of laws and the availability of technical and scientific resources at EU level has not been adequately**

considered. In too many cases, there are expertise "gaps" in implementation processes and mechanisms because of the scale and ambition of risk management laws. EU policies to manage conflicts of interest that exclude eminent and relevant experts from academia because they work with knowledge generators in the private sector, exacerbate these problems.

- **Major changes in the risk management philosophy of the EU have made it more difficult to make high-quality implementation decisions.** A shift from mitigating well-established risks posed by production processes and a small number of product technologies to managing uses of technologies or to creating a better world, poses major problems for implementation. It increases the number of implementation decisions; requires more complex, and often lower quality, secondary legislation; reduces the predictability of regulatory decisions; and exposes gaps in expertise and in bureaucratic, technical, and scientific capacity.

- **Too many scientific assessments – and the risk management measures they inform – continue to be unduly influenced by outdated scientific knowledge and social concerns.** Whereas science moves on continuously, the influence of old, discredited studies or assumptions or models that no longer form part of the body of scientific knowledge lives on within implementation processes. This failure to discard the concerns of the past, that science no longer supports, plays a major role in undermining the quality of scientific assessments.

- **Lack of awareness about the nature of implementation decisions has impeded the process of governance reform.** Implementation of risk management laws is not a simplistic process of technical decision-making, whereby officials adhere to the requirements of quasi-bureaucratic processes to deliver deterministic outcomes. Implementation decisions are better considered as being regulatory decisions, and, as such, require decision-makers to demonstrate a convincing intervention logic derived from credible evidence; to assess alternative options; to examine costs and benefits; and, to undertake rigorous ex post reviews.

- **Finally, the EU institutions continue to conceive of the implementation of risk management laws within the contextual framework of an outdated model of law-making.** In the past, EU legislators set out requirements in directives

and mandated implementation onto Member States. For the management of risk, this is no longer the case. Requirements are typically set out in EU regulations and implementation is carried out primarily using centralised bodies, processes, and mechanisms. Despite this, the older model still influences the EU's Better Regulation policy and other important mechanisms of EU governance. There continues to be a lack of awareness about the scale, nature, and importance of the EU Administrative State amongst opinion-formers and policy-makers and, as a result, political commitment to address the challenges it poses remains limited.

Although resolving these problems will not be easy, a successful programme of reform would generate significant benefits for the EU and institutions. It is a natural complement to the Commission's widely admired Better Regulation policy, and would demonstrate a continued commitment to better law-making. It would limit the risk of regulatory failure, helping to deliver social goals and strengthen legitimacy. Incentives to innovate would be strengthened too. Reform would, by strengthening procedural rights, also consolidate the EU's legal order, highlighting its support for rules-based trade. Finally, effective reform would demonstrate leadership and highlight the importance of the EU for the protection and prosperity of citizens in an era of euroscepticism.

7. Recommendations

A programme of reform has been identified that reflects the mandate of the European Risk Forum (ERF) and focuses on the implementation through the EU Administrative State of risk management laws. It targets the weaknesses in its governance identified by the ERF's research.

The reforms are designed to change behaviours within a complex institutional context. As such, they encompass changes in political commitment, the legislative framework, institutions, and guidelines, and recognise that reforms take time to develop, accept, and implement.

The reforms build on the many good practices and initiatives already present within the EU institutions. The reforms complement each other. Taken together, they target the underlying causes of the failings of the EU's approach to implementing risk management laws, along

with weaknesses in implementing mechanisms, and the assessment and preparation processes and institutions that support them.

Achieving change will take time to deliver fully. The programme recognises this. Some reforms can be delivered in the next 1-3 years; others will take longer. Ideas for immediate reform are also set out in the Executive Summary of this monograph.

7.1. EU Institutions – Political Commitment

Recommendation 1: Building on its commitment to and endorsement of Better Regulation, the Council of EU Ministers should affirm its support for the greater use of proportionality in law-making at all stages of the policy cycle by, for instance, adopting dedicated conclusions. As well as recognising the importance of proportionality as a general principle of good law-making, the Council should recognise its importance for improving the quality of implementation decisions.

Recommendation 2: Collectively, the EU institutions should, through a revision of the Inter-Institutional Agreement on Better Law-Making, clearly define criteria for regulatory quality to be met at all stages of the policy cycle. The institutions should also make a formal commitment to:

- Design and implement risk management measures that protect human health, public safety and the environment while promoting sustainable economic growth, innovation, and job creation.

- Use the best available science as the pre-eminent knowledge input to inform and guide risk management decisions, at all stages of the policy cycle (legislation and implementation) to protect human health, public safety, and the environment. In so doing, they are recognising its unique characteristics as a source of insights and evidence, and are relying on globally accepted standards of regulatory management and good administration.

- Require scientific assessments, including risk assessments, to fully reflect real-world experience and normal conditions of usage and exposure.

- Communicate fully, objectively, and in a timely manner the potential risks posed by substances, technologies, and processes whilst recognising explicitly that a zero-risk society is neither possible nor desirable.

Recommendation 3: The European Commission should develop a new set of political commitments and objectives for the Better Regulation policy that strengthen the following commitments:

- base decisions on the best available evidence;
- promote innovation, whilst ensuring a high standard of protection;
- apply Better Regulation principles and guidelines to all parts of the policy cycle, including implementation decisions made through the EU Administrative State;
- require all interventions to demonstrate that benefits justify costs, that net risks are reduced and that the least restrictive means of achieving the regulatory goal have been used;
- ensure that new and existing interventions are proportionate and coherent with other parts of the regulatory framework; and,
- employ decision-making processes and adopt measures that are effective, proportionate, predictable, transparent, accountable, simple, and achieve a high degree of public consultation.

7.2. EU Institutions – Legislation

Recommendation 4: The EU Legislature should, building on the work of the European Parliament, develop and adopt a comprehensive Law of Administrative Procedures. This should embed the principles of good administration into law, strengthen judicial review, provide legally enforceable standards and procedural rights, and encompass all significant rule-making and adjudication processes used through the EU Administrative State.

7.3. European Commission – Institutional Architecture

7.3.1. EU Risk Assessment Agencies

Recommendation 5: Building on the Inter-Institutional Joint Statement and Common Approach on Decentralised Agencies, the EU institutions should establish common decision-making processes and standards for the risk assessment agencies based on established principles of good governance, Better Regulation, and good administration. These should encompass for all agencies:

- Pre-submission hearings;
- Agreements with affected parties to define in advance data requirements;
- Independent administrative appeals mechanisms for affected parties with a wide scope of reviewable decisions (substantive and procedural, including scientific assessments) and extensive powers of redress;
- Expert panels for scientific assessments;
- Common standards for scientific integrity;
- Scientific hearings and extended consultation for affected parties;
- Common standards for developing and adopting substantive guidance that comply with the requirements for law-making set out in the Better Regulation guidelines; and,
- Independent peer review of significant scientific assessments.

7.3.2. Scientific Advice Mechanism and Oversight Functions

Recommendation 6: The European Commission should revise the mandate of the Scientific Advice Mechanism to establish explicit and formal oversight functions to ensure the effective functioning of the entire scientific advisory system. Such functions should be exercised under the responsibility of the SAM Group of Chief Scientific Advisors. Among

the new responsibilities should be 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 Administrative State, including agencies. Adequate resources, staff, and expertise should be allocated for this purpose to ensure compliance, by all directorates and agencies, with common policies and guidelines. Scientific oversight must, moreover, be independent of Commission services, EU agencies, and bodies.

7.3.3. Secretariat-General and Regulatory Overlap

Recommendation 7: Independently of regulating directorates or EU agencies, the Secretariat-General should be responsible for resolving problems of regulatory overlap. Decisions should be made using transparent processes that ensure extensive consultation of affected parties and a clear consideration of the costs and benefits of alternative solutions. There should be a preference, when making adjudications, for certainty, accumulated wisdom, and benefits justifying costs.

7.3.4. Scientific Advice Mechanism and Benchmarking

Recommendation 8: The European Commission should revise the mandate of the Scientific Advisory Mechanism to incorporate periodic benchmarking of the time and cost of product approval processes and to draw conclusions and recommendations for structural improvements, as appropriate.

Initially, this should focus on identifying the actual time needed to carry out the final assessment phase of specific processes, making comparisons over time. This should then be extended to encompass the time needed to undertake testing, so as to demonstrate compliance, and, through comitology, to achieve final approval. Wherever possible, comparisons should also be made with global peers.

Eventually, benchmarks should also encompass comparisons of the cash costs of testing and achieving approval.

7.3.5. Regulatory Scrutiny Board and Scope of Review

Recommendation 9: The European Commission should expand the mandate of the Regulatory Scrutiny Board (RSB) to include the implementation of risk management decisions by substantive guidance or comitology. This should ensure that the RSB oversees the interventions made through the EU Administrative State. As a part of this, the RSB's mandate should encompass oversight of the quality of scientific evidence used to justify individual risk management measures. To this end, organisational and procedural arrangements should be designed to ensure the closest coordination possible between the RSB and the Scientific Advice Mechanism.

Transparent mechanisms based on objective criteria should be put in place to tailor the review activity of the RSB so as to ensure proportionate yet effective scrutiny.

7.4. European Commission – Policies

7.4.1. Proportionality Principle

Recommendation 10: The European Commission should, in the form of a communication, define the meaning and usage of a Proportionality Principle. The communication should be informed by legal requirements set out in the Treaty and in the jurisprudence of the EU Courts. It should explain how the principle should be used to improve the quality of regulatory decision-making, including the implementation of risk management laws made through the EU Administrative State.

7.4.2. Quality, Collection, and Use of Scientific Evidence

Recommendation 11: The European Commission should develop and adopt for example, in a new 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.

- 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 weight-of-evidence; use of peer review; and, provision of an independent right of appeal, prior to dissemination of the findings of significant scientific assessment.

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

7.4.3. Selection of Scientific Experts

Recommendation 12: The European Commission should set out, for instance, in a new decision, the key principles for the selection of scientific experts and for the operation of scientific committees. These should be minimum standards and should apply to all agencies and directorates, and all forms of scientific committee including Technical Working Groups. Within its provisions, the decision should:

- Require scientific assessments to be carried out by scientific experts who meet agreed standards of eminence, excellence, and relevance.

- Allow all relevant scientists who meet agreed criteria of eminence, excellence, and relevance to be eligible for selection.

- Establish transparent selection processes to identify all forms of material conflicts of interest that may create bias and are likely to be relevant to the specific work of the group. This should include, but should not be limited to: beliefs, ideals, ideologies, political affiliations, support from or links to interest groups; financial interests; and, personal factors.

- Develop procedures to manage conflicts of interest, such that the most appropriately qualified experts are only excluded in very limited circumstances, such as a credible risk of direct current financial benefit or substantial evidence of personal beliefs or commitments or ideological perspectives that suggest predetermination.

- Require membership of scientific committees to be constituted so as to ensure that decision-makers have access to a range of different, but relevant, types of scientific experts from different scientific disciplines.

- Require all outcomes of scientific assessments to be subject to independent peer review. All draft assessments should be reviewed procedurally whilst significant assessment should be subject to an additional substantive review.

7.5. European Commission – Guidance

7.5.1. Scientific Integrity Standards

Recommendation 13: Working under direction of the central oversight body (as referred to in Recommendation 6 above), independent committees of eminent scientists should draw up all significant technical guidelines required to support the Commission-wide policies for the quality of scientific evidence and risk analysis, and to ensure that scientific integrity is respected. This process should ensure that guidelines are independent of political considerations, that they are based on cutting-edge science; that they reflect lessons learned from retrospective evaluation of scientific evidence; and that they embed the expertise of the scientific community.

7.5.2. Risk Management – Precautionary Principle

Recommendation 14: The European Commission should develop supplementary guidelines that clarify the role of the Precautionary Principle in 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 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. Precautionary measures, if considered, should be proportionate and subject to review.

The guidelines should remind all agencies and directorates of these requirements and highlight questionable practices that appear to use forms of the Principle in scientific assessments. These include basing opinions on "unknowns" or low-quality studies or

studies that are "outliers" instead of the weight-of-evidence provided by extensive data packages; changing defaults and assumptions without scientific justification; and using hypothetical or unrealistic exposures.

7.6. European Commission – Better Regulation Guidelines

7.6.1. Legislative Design

Recommendation 15: The European Commission should revise the Better Regulation guidelines to expand and strengthen requirements to consider the design of proposed risk management legislation. New requirements should require officials to assess rigorously:

- the extent to which objectives are measurable, the credibility of performance metrics, and, future ex post evaluation of objectives;
- implementation processes and mechanisms;
- policy coherence;
- regulatory overlap;
- the role of Member States in assessment of risks and preparation of draft measures;
- the regulatory costs of using hazard rather than risk to deliver a high standard of protection and to reduce net risk; and,
- the balance between the ambitions of the measure and available expertise and resources.

7.6.2. Impact Assessment of Implementing Measures

Recommendation 16: The European Commission should revise the Better Regulation guidelines to further strengthen the focus on comitology and to encompass within their scope all substantive guidance developed by the Commission and EU risk assessment agencies.

To that end, the Commission should draw up and enforce transparent mechanisms based on objective criteria (such as thresholds or filter or "triage" checklists) to determine the type and depth of the assessments so as to ensure proportionate yet effective application of Better Regulation principles and tools. This should ensure that all significant implementing measures are subject to an ex ante impact assessment and meaningful consultation.

At the same time, the Commission should require all implementing measures justified by the application of the Precautionary Principle to undergo a comprehensive impact assessment and to contain an explicit binding review clause.

Similarly, all implementing measures that ban or restrict the use of a substance or technology should always undergo a comprehensive impact assessment, including consideration of substitution or substitutes. This should enable regulators to understand better the costs and benefits of implementing measures, including risk-risk and risk-benefit trade-offs, as well as dynamic impacts.

7.6.3. Implementing Decisions – Tool Kit

Recommendation 17: The European Commission should develop a new tool kit to help officials undertake *ex ante* impact assessments of proposed measures to implement risk management laws. It should emphasise the need to consider whether benefits justify costs; cost effectiveness of measures; impact on net risk, including risk-risk trade-offs; dynamic regulatory impacts; and value chain impacts.

7.6.4. Cost Effectiveness Analysis

Recommendation 18: The European Commission should require greater use of cost-effectiveness analysis when conducting ex ante impact assessments of proposed implementing measures.

Cost effectiveness analysis (CEA) provides a structured framework for helping regulators to compare the quantified benefits of policy actions with their costs. Used well, CEA forces policy-makers and regulators to quantify rigorously the health or environmental benefits of prospective government actions to reduce risks. When properly constructed, CEA provides clear metrics for decision-makers, facilitating comparisons between different

ways of managing the same problem, such as reducing risks to human health or public safety. CEA data, derived from a range of risk management actions, can also play a major role in the governance of risk, helping to identify the most efficient ways in which resources can be used to save or improve lives.

7.6.5. *Public Consultation of Implementing Measures*

Recommendation 19: Based on the filtering mechanism set out in Recommendation 16 above, the European Commission should systematically include all major implementing measures by the Commission and the EU agencies under the scope of the Commission's minimum standards of consultation. Implementing measures subject to consultation should include substantive guidance drawn up by the Commission or the EU agencies, including requirements that embed risk management assumptions, and all implementing and delegated acts for which an impact assessment is carried out. This will require the minimum time for consultation for a comitology measure to be increased from four to twelve weeks.

7.6.6. *Ex Post Evaluation of Implementing Decisions*

Recommendation 20: The European Commission should broaden the scope of ex post evaluations to encompass all major implementation decisions. This would recognise the pivotal role played by these decisions in achieving risk management objectives. Reviews should encompass consideration of the effectiveness and impact of substantive guidance and comitology decisions. They should also identify "horizontal" impacts, such as stigmatisation, value chain distortions, capitalised costs, and defensive R&D.

7.7. European Parliament

Recommendation 21: The European Parliament should expand the availability of its Research Service (EPRS) resources and revise parliamentary rules to ensure a more rigorous and robust review of implementing decisions, when the EP plays a formal role in scrutiny to ensure their compliance with agreed quality and due process standards.

7.8. Business

Recommendation 22: Companies and trade associations should invest in the development of socio-economic analyses (SEAs). These explain the complex contribution that industries, their technologies, and their value chains make to modern societies. SEAs highlight the public benefits of business activity, transparently contributing to public policy debates, informing opinion-formers, and helping regulators make better, more balanced decisions.

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

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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 awareness of risk management issues at EU level.

In order to achieve this, the Forum applies the expertise of a well-established network of experts on "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.

For more information visit **www.riskforum.eu** or contact:

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