EUROPEAN RISK FORUM – POLICY NOTE 33

THE EU'S ADMINISTRATIVE STATE: NATURE, SCALE AND IMPLICATIONS OF IMPLEMENTING RISK MANAGEMENT LAW THROUGH SCIENCE, REGULATION, AND GUIDANCE

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1. EU Administrative State and Risk Management[1]

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

To a large extent, this 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. Risk regulation, and the implementation of risk management laws, play a crucial role in this respect.

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 co-ordinate action in Member States);

- **Growth in the use 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 [2] needed to implement new, ambitious risk management laws; and,

[1] This Policy Note draws from the Executive Summary of the ERF Monograph 'Risk management and the EU's Administrative State: Implementing Law through Science, Regulation, and Guidance' (2019), available at http://www.riskforum.eu/publications.html.

- **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 include:

- 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; and,

[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 license renewals.

- 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 co-ordinated 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 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 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 diminution 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 number 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 out-dated 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 out-dated model of law-making.

Addressing these structural shortcomings calls the EU institutions upon to leverage "Better Administration" as the natural complement to their traditional EU Better Regulation strategy – a necessary recalibration that bears great potential for Europe's economy and society.

6. Recommendations

The ERF Monograph[3] 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 institutions that support them.

[3] ERF Monograph 'Risk Management and the EU's Administrative State: Implementing Law through Science, Regulation, and Guidance' (2019)

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

European Risk Forum

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

In order to achieve this, the Forum applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

The Forum believes that:

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

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

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

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

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

The Forum works with all of the EU's institutions to promote ideas and debate. Original research is produced and is made widely available to opinion-formers and policy-makers at EU-level. As an expert group, the Forum brings together multiple sources of evidence (such as the experience of practitioners and policy-makers; non-EU good practices; and academic research) to assess issues and to identify new ideas. Indeed, direct engagement with opinion-formers and policy-makers, using an extensive programme of conferences, lunches, and roundtables, is a feature of the Forum's work.

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

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