



MANAGEMENT OF RISK AND THE EU'S ADMINISTRATIVE STATE

HIGHLIGHTS NOTE 09

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

This ERF Highlights Note examines the origins of the EU's administrative state. It explains its nature and rationale. It explores the problems its piecemeal development creates for governance and good administration. Finally, it identifies a small number of reforms that could, if implemented fully, begin the process of improving governance and ensuring good government.

ADMINISTRATIVE STATE

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 and desires of citizens. In many instances, the achievement of these policy goals requires extensive primary legislation combined with complex implementation processes.

To meet these new, demanding requirements, an "administrative state" has emerged, taking countless decisions on a daily basis, so as to achieve over-arching, complex social or economic goals. Many of these technical, implementation decisions involve rule-making or adjudications that affect the opportunities and freedoms of citizens and businesses, and thus the ultimate success of the underlying social and economic policy. Within this

context, the executive function of government is frequently endowed with legislative and judicial powers, often breaking down the traditional separation of powers designed to protect citizens from poor quality or arbitrary decision-making.

EU ADMINISTRATIVE STATE AND RISK MANAGEMENT

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

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

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

- **Legislators have made increasing use of direct, centralised risk management processes and laws (Regulations),** focusing on making decisions at EU-level rather than using Directives to co-ordinate activity in Member States;

- **Secondary legislation has become increasingly complex and ambitious**, as policy-makers have sought to manage the usage of materials throughout the economy, to reduce low frequency risks, and to pursue ambitious social goals alongside risk reduction. Complex secondary legislation requires extensive substantive guidance, an informal type of rule-making, if it is to be implemented effectively;

- **New legislation, such as recent rules to manage risks posed by the usage of chemicals, biocides and crop protection products, requires very large number of legally-binding regulatory decisions**, as substances and their uses are dealt with on a case-by-case basis;

- **New EU institutions, most notably agencies, have been set up by the European Commission to assist the process of implementing new, ambitious risk management laws.** Although most of these agencies are primarily involved in risk assessment, they also play a role in rule-making and adjudications. Risk assessment agencies issue substantive guidelines, a form of soft law, clarifying the meaning or scope of laws or defining the technical requirements that businesses must meet, if their products or materials or services are to satisfy standards of safety or quality or efficacy. Because these often embed assumptions about social acceptance of risk or ways to manage potential harms, this is a hidden form of rule-making. Alongside this, agencies advise the European Commission about the safety of materials or products on a case-by-case basis, forming part of the formal regulatory process.

- **Comitology, the traditional mechanism for providing legally-binding implementation measures, has been expanded to encompass the large number of formal rule-making and adjudication decisions needed to implement new, ambitious, wide-ranging risk management laws.** 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, including a lack of transparency; barriers to meaningful input; absence of a public record; gaps in expertise; ability to rely on information not made available to the public; limited obligation by decision-makers to explain the legal and factual bases of their decisions; and politicisation by Member States.

- **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. Adherence to technical standards, set by voluntary EU-level standard-setting bodies, provides a means of demonstrating compliance. Historically, these 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 adjudications that stigmatise particular products.

GOVERNANCE PROBLEMS

At EU-level, an administrative state has emerged without any formal strategy or plan. Its decision-making mechanisms and institutions are the result of a piecemeal approach, reflecting different and separate policy objectives, and older approaches designed to resolve different problems. Taken together, these changes have exposed major weaknesses in the governance of the EU's institutions. These include:

- **Citizens and business are faced increasingly with direct action by the EU's institutions without having corresponding legally enforceable procedural rights to challenge them.** There is no Law of Administrative Procedures at EU-level that enshrines in law the principles of good administration (transparency and consistency; public participation; public record; and accountability) and places legally enforceable limits on the way in which executive power is used when implementing laws. Moreover, the good regulatory principles and practices set out in the Inter-Institutional Agreement on Better Law-Making do not encompass substantive guidance and other formal and informal implementation mechanisms.

- **Existing “soft law” administrative procedures and requirements of the EU institutions do not, on their own, sufficiently protect the right of citizens and businesses to good administration;**

- **Judicial review by the EC courts has not created a framework of procedural standards to match the growth in the power of the administrative state at EU-level.** Indeed, when considering the management of harms, the courts have tended to apply a limited review and usually accept the discretion of the executive function, leading, on some occasions to the acceptance of procedural approaches, such as the use of precaution without evidential standards or the use of social concern rather than science to trigger government action, which reduce legal certainty and increase unpredictability.

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

- **Administrative guidance, including the Better Regulation Strategy is, moreover, a form of soft law and does not create enforceable procedural rights** for citizens and businesses affected by decisions made by the EU.

ERF OBSERVATIONS

Citizens lose out if complex risk management rules are implemented poorly. Poor governance of the EU's administrative state increases the likelihood of "regulatory failure", limiting the socio-economic benefits of public policy. Decisions that are not of high quality often fail to deliver social goals or may generate rules where the cost of regulation exceeds its benefits or where there are substantial negative unintended consequences.

On too many occasions the implementation of risk management rules has created significant problems for businesses. Costs and benefits of measures are not always properly considered; poor quality substantive guidance has increased Defensive R&D and new product development costs, as well as stigmatising technologies and expanding the scope of laws; opacity, politicisation of decision-making, and administrative discretion has created unpredictability. Such failings limit returns from existing investments, undermine incentives to innovate and weaken the attractiveness of the EU for the allocation of capital.

Action is needed to reform the governance of the EU's administrative state. For this to be achieved, attitudes to law-making must change amongst EU-level opinion-formers and policy-makers: shared beliefs about the governance of law-making, and about the scope and complexity of their application, continue to be influenced by ideas that no longer reflect current practice. Directives have been replaced by Regulations; decentralised implementation has given way to centralised institutions and processes; and the scientific rationale for risk reduction is too often replaced by value judgements and social aspirations.

Reform of the institutions and mechanisms used by the EU to implement risk management laws offers an opportunity to further develop the Better Regulation strategy, to demonstrate a commitment to the rule of law, and to demonstrate a willingness to change.

A small number of reforms, if implemented together, would begin the process of improvement:

- *Work with the European Parliament to develop and adopt a comprehensive Law of Administrative Procedures* – this should embed the principles of good administration into law, provide legally enforceable standards and procedural rights, and encompass all significant rule-making and adjudication processes;
- *Revise the Better Regulation integrated guidelines to strengthen further the focus on Implementing and Delegating Acts* (the revised forms of comitology);
- *Expand the remit of central quality oversight of the Regulatory Scrutiny Board to encompass all of the processes used to implement risk management legislation;*
- *Encourage the EU's risk assessment agencies to develop a set of formal best practice standards for the development of substantive guidance* – this could be achieved by working with the EU-ANSA network, for example;
- *Commission an independent evaluation of the coverage, nature, powers, and adequacy of existing administrative appeals procedures* – this should focus on decision-making mechanisms used to make formal, legally-binding rules and adjudications. Informal adjudication mechanisms should also be reviewed.

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Richard Meads, the European Risk Forum's Rapporteur, wrote this Highlights Note. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or its members.