EUROPEAN RISK FORUM - POLICY BRIEF 08

COMITOLOGY AND THE MANAGEMENT OF RISK AT EU-LEVEL

2009

EXECUTIVE SUMMARY

At EU-level and throughout the OECD area, many public risk management objectives are achieved using a complex, multi-stage approach. Framework legislation sets out the social goals to be achieved, identifies the hazards to be controlled, and defines the level of social acceptance of risk. Technical regulatory decision-making processes implement legal requirements and deliver the goals set out in primary law. At EU-level, four different processes are used to implement framework risk management laws: guidelines; voluntary standards; decentralised decisions by Member States; and comitology.

Comitology combines extensive scientific and technical input from the European Commission (the executive function) with political oversight from the EU's Member States and, increasingly, the European Parliament. It is the most widely used form of rule-making at EU-level, providing the EU's institutions with a speedy and flexible process for establishing the detailed and legally binding rules needed to implement framework laws and manage risks, whilst maintaining political consensus. Despite recent efforts to improve the process, comitology continues to exhibit major structural weaknesses. Possible reforms include:

- Develop a formal Commission policy recognising the role that comitology plays in the management of risk and defining the procedural rights of participants;
- Establish an administrative right of appeal for persons directly affected by the comitology process;
- Extend the scope of the Commission's minimum standards for consultation to include major comitology decisions;
- Implement and publish mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments that inform the comitology process;
- Revise the Commission's impact assessment guidelines so that they include criteria and methods for identifying 'major' comitology decisions and their complex impacts, and they outline the main issues that impact assessments must cover to inform comitology decisions fully;
- Require all additional scientific, technical and expert information used in the committee phase to be subject to independent assessment
- Publish all scientific and technical evidence used to determine the basis of implementing measures approved using the comitology process;
- Ensure that the existence of all documents, whether confidential or not, is made known to the public via the Comitology Register;
- Publish the forward planning programme for comitology decisions and improve the quality of summary records of comitology meetings;
- Allow systematic participation in committee discussions by affected stakeholders

1. BACKGROUND

Throughout the OECD area, many public risk management objectives are achieved using a complex, multi-stage approach. Framework legislation, normally derived through a political process, sets out the social goals to be achieved, identifies the hazards to be controlled, and defines the level of social acceptance of risk. A number of procedures and tools are then used by governments to implement legal requirements and to deliver the goals set out in primary law[1]. These implementation activities are often categorised as "technical regulatory decision-making processes".

Technical and administrative processes, often involving extensive regulatory and scientific activity, are used by governments to make the large numbers of heterogeneous case-by case decisions needed to manage complex risks to human health, public safety, and the environment over long periods of time. Indeed, 'technical' regulatory risk management decision-making has become one of the most important ways in which social goals are met in most OECD countries.

At EU-level, four different technical processes are used to implement framework risk management laws: guidelines (a form of 'soft law', mainly issued by EU-level agencies[2]); voluntary standards (drawn up by expert, independent bodies under the "New Approach" legislation[3]); decentralised decisions (direct implementation by Member States of EU laws[4]); and comitology.

Comitology combines extensive scientific and technical input from the European Commission (the executive function) with political oversight from the EU's Member States and, increasingly, the European Parliament. It is the most widely used form of rule-making at EU-level, providing the EU's institutions with a speedy and flexible process for establishing the detailed and legally binding rules needed to implement framework laws, whilst maintaining political consensus. It is used extensively to manage risks posed by technologies and lifestyle choices, determining highly detailed matters such as nutrition profiles, approval of new pharmaceuticals, hazard classifications of chemicals, emission limits, health claims for foodstuffs, approval of new biotechnology products, composition of positive lists for additives used in foods, specific uses of chemical or metallic substances, and levels of residue limits for veterinary drugs.

Indeed, the use of comitology is likely to expand significantly over the next decade, as the EU implements complex, new risk management laws, such as those designed to manage the risks posed by chemical substances and their use, and those that seek to cut carbon emissions across a wide range of business sectors.

At EU-level, the quality of outcomes and legitimacy of the overall law-making process depends increasingly on the way in which the EU's institutions use comitology.

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[1] At EU-level primary laws correspond to secondary legislation, such as EU Directives or Regulations: the EU treaty is defined as the primary level of law.

[2] See European Risk Forum 'Guidelines and the Growth of the Regulatory State at EU-level' (Policy Brief 06, 2009)

[3] Under the "New Approach", framework laws specify essential requirements. International standard-setting organisations then draw up detailed standards that define, frequently for different products or components, how the essential requirements may be met. This approach has been widely used to manage risks posed by complex forms of equipment, such as electrical, electronic and mechanical products.

[4] 'Decentralised' implementation occurs when risk management laws take the form of EU Directives or when an EU Regulation makes use of mutual recognition between Member States.

2. COMITOLOGY AND RISK MANAGEMENT

Comitology emerged in the 1960s, as the EU began to implement the complex provisions of its agricultural policies. 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 the use of this highly effective tool led to its formalisation through Council Decisions in 1987, 1999, and 2006.

Conceptually, the term 'comitology' describes the use of formal committees, comprised of Member States representatives, to oversee the use by the European Commission of implementing powers[5]. Individual framework laws determine the nature of the Commission's implementing powers, and prescribe appropriate oversight mechanisms, including the use of comitology committees.

As an approach to managing risk at EU-level, however, 'comitology' is a multi-stage process, involving:

- **Preparation of implementing measure** – this phase is undertaken by the Commission and ideally covers problem definition, identification of objectives, development of options, analysis of impacts, and comparison of options. Evidence to support the need for action, and the nature of the implementing measure is gathered from technical working groups (formed by Member States), independent scientific committees, EU-level agencies, other experts, and expertise within the European Commission.

- **Approval of implementing measure** – the Commission submits its proposed measure to a Standing Committee made up of representatives of the Member States. Using qualified majority voting, the committee decides whether to approve the proposed measure.

- **Scrutiny of the measure** – for most risk management policies, draft implementing measures, if approved by the Standing Committee, are sent to the European Parliament and Council for scrutiny. Either institution can block the measure, although an absolute majority is required in the EP[6].

Over more than four decades, comitology has played a vital role in building the EU's Single Market and in managing risks to human health, public safety, and the environment posed by technologies and lifestyles. It has enabled very large number of complex, technical decisions to be made quickly; it has allowed EU laws to adapt flexibly to technological progress; and it has maintained political consensus and commitment amongst the Treaty partners. Indeed, more than 2,500 rules are adopted each year by the EU using comitology, involving nearly 300 committees.

As comitology continues to grow in importance as a mechanism for managing risk at EU-level, whilst confronting a growing number of controversial issues, the challenge is to ensure that the overall process is able to meet modern standards of regulatory quality.

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[5] In this paper, we focus on Regulatory Committees, the most commonly used form of comitology for the management of risk. Other comitology committees, as set out in framework laws and Council Decisions, provide the Commission with advice, but are infrequently used to manage risks.

[6] This is known as the "Regulatory Procedure with Scrutiny" (RPS), and applies in policy areas where the EP and Council make framework laws on the basis of co-decision. This encompasses most major risk management policies.

3. COMITOLOGY AND REGULATORY QUALITY AT EU-LEVEL

Since the late 1990s, action has been taken by the EU's institutions to reform and improve the operation of the comitology process. Recent Council Decisions have improved transparency by placing committee documents in a public register and publishing an annual report, drawn up by the Commission, describing the work of the committees in the previous year. Technical working groups, made up of experts from Member States, and used to provide scientific and technical input have been replaced in some policy areas by independent scientific committees or EU agencies.

Moreover, since 2008, major comitology decisions have been brought within the scope of the Commission's impact assessment process. At the same time, recent decisions by the ECJ have sought to place limits on the scope of implementing decisions, seeking to ensure that they should not go beyond the objectives of legislation and should be consistent with such objectives. Finally, MEPs have been given greater scrutiny powers since 2006, enabling them to veto proposed implementing measures in certain limited circumstances;

Despite these improvements, the comitology process continues to exhibit serious structural weaknesses. The Commission's existing regulatory process management standards are not applied adequately to implementing measures. There are no evidential standards to determine the admissibility of technical or scientific evidence used to develop implementing measures. Comitology falls outside the Commission's minimum standards for consultation, limiting the possibility of ensuring that poor quality evidence and measures are properly scrutinised and reducing comprehensive access to real world experience. And, impact assessment tools used by the Commission for this specific phase of the decision-making process do not fully take into account complex regulatory impacts, such as demand stigmatisation, often triggered by comitology decisions.

Transparency is also inadequate in too many cases. Decision-making processes are opaque; discussions of committees are confidential; and access to documents is incomplete and cumbersome. Recent research[7] highlights a failure of the EU institutions to make documents available, whilst the ECJ reversed decisions by the Commission to refuse to make available scientific documents used in the development of an implementing measure, criticising the failure to make documents available for scrutiny.

Other failings include a lack of detailed minutes of meetings, lack of an easily accessible forward planning programme, the lack of a full justification for selecting specific measures (and for rejecting scientific evidence), the use of scientific evidence in Standing Committee meetings that has not been assessed by independent experts, and a lack of awareness amongst committee members of the costs and benefits of proposed implementing measures. Alongside these concerns, the process lacks of predictability and timeliness when faced with controversial risk management problems, whilst gaps in expertise amongst some Member States, as well as weaknesses in checks and balances, create scope for national interests to 'capture' decision-making processes in selected areas, amplifying existing problems of politicisation and regulatory uncertainty.

[7] See, for example Brandsma, Curtin, and Meijir 'How Transparent are EU Comitology Committees in Practice' (European Law Journal, November 2008)

4. RECOMMENDATIONS

Comitology has become one of the most important mechanisms for delivering the EU's risk management goals. Despite efforts to improve the process, it continues to exhibit major structural weaknesses. Possible reforms include:

- **Develop a formal Commission policy recognising the role that comitology plays in the management of risk and defining the procedural rights of participants,** including rights to be consulted, to participate in a structured process with time limits, and to be fully informed of decisions;

- **Establish an administrative right of appeal for persons directly affected by the comitology process,** covering proposed measures and evidence;

- **Extend the scope of the Commission's minimum standards for consultation to include major comitology decisions,** including risk management;

- **Implement and publish mandatory written principles that define the quality of studies, information, and data to be used in scientific assessments that inform the comitology process**. These principles should require studies, information, and data to be based on widely-accepted sound and objective scientific practices (the "scientific method") including peer reviewed science.

- **Revise the Commission's impact assessment guidelines so that they include methods for identifying 'major' comitology decisions and complex regulatory impacts,** including demand stigmatisation, and set out the main issues that assessments must cover to inform comitology decisions fully;

- **Require all additional scientific, technical and expert information used in the committee phase of comitology to be subject to independent assessment,** including peer review;

- **Publish all scientific and technical evidence used to determine the basis of implementing measures** approved using the comitology process;

- **Ensure that the existence of all documents, whether confidential or not, is made known to the public via the Comitology Register**, providing the public with the opportunity to challenge comitology procedures;

- **Publish the forward planning programme for comitology decisions and improve the quality of summary records of the meetings** to record all of the issues on the agenda, to accurately record areas of contention during the discussions, and to provide a full and reasoned explanation of their decisions;

- **Allow systematic participation in committee discussions by affected parties**

2009

This policy brief was written by Richard Meads, the European Risk Forum's rapporteur, with help from members of the Forum. However, the views and opinions expressed in this paper do not necessarily state or reflect those of the European Risk Forum.

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);

- 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, the Forum believes, 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 practioners 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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