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 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.
EXECUTIVE SUMMARY

The Commission’s power to implement legislation, as conferred by the European Parliament and the Council of the European Union, is performed with the assistance of committees made up of representatives of Member States. This process is known as “comitology”. Before the adoption of implementing measures, these committees give their opinion on the draft measures and act as a conduit between the Commission and national administrations. The comitology process can therefore be seen as a check by Member States on the exercise by the Commission of its delegated executive power.

Comitology 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.

Despite efforts to improve the process, comitology continues to exhibit major structural weaknesses, including a lack of transparency. Without reform these weaknesses pose major challenges for future regulatory quality and for the maintenance of public trust in the legitimacy of EU rule-making.

Although comitology plays a vital role in advising the Commission on legislation and determining the implementation of draft measures, it is important that the procedures followed by the committees are open to public review so as to strengthen accountability. As shown, recent case law has increased access to documents generally and has also laid down rules on providing greater access to scientific and technical evidence.

Further improvements to aid transparency in comitology could include:

- **Ensure that the existence of all documents, whether confidential or not, is made known to the public via the Comitology Register**, without this information the public will not have a full understanding of the decision-making process nor will they have the opportunity to challenge comitology procedures;

- **Improve the quality of summary records of the meetings** to record all of the issues on the agenda and accurately record areas of contention during the discussions;

- **Post notices of upcoming meetings and unofficial Working Group meetings on the committee websites**;

- **Allow participation in committee discussions by stakeholders**;

- **Ensure a consistent approach between committees as to what information is placed on the internet** in either Word or PDF format;

- **Publish scientific and technical evidence used to determine the basis of legislation**.
1. BACKGROUND

The Commission’s power to implement legislation, as conferred by the European Parliament and the Council of the European Union, is performed with the assistance of committees made up of representatives of Member States. This process is known as “comitology”. Before the adoption of implementing measures, these committees give their opinion on the draft measures and act as a conduit between the Commission and national administrations. The comitology process can therefore be seen as a check by Member States on the exercise by the Commission of its delegated executive power.

Comitology 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.

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, such as transparency and openness.

2. COMITOLGY AND TRANSPARENCY

The Council’s “Comitology Decision” of 1999¹ (as amended in 2006²) sets out the relationship between the Commission and the committees. For a number of years, there had been complaints by the European Parliament and other stakeholders within the EU that the procedure lacked transparency. The Comitology Decision was set to address this issue of transparency by making committee documents easily accessible to the general public since, as of 2003, committee documents are recorded in a public register available on the internet (Comitology Register). Article 7(5) of the Comitology Decision specifically states that references to documents sent to the European Parliament shall be made public. From 2000, the Commission has also published an annual report of the work of comitology committees during the previous year.

Despite improvements to the comitology system, it can be argued that the procedure used to implement legislation is still not transparent enough. A study published in the European Law Journal in November 2008 found that the comitology system could be much more transparent. By comparing the Commission’s annual report of the

comitology committees against the documents actually made available on the Comitology Register, they found that, “About 45% of attendance lists are missing, 35% of the agendas are not published, an astonishing 95% of the draft measures are not disclosed and about 32% of the summary records are not available online. When summary records are available, the vast majority of about 85% is of poor quality.”\(^3\) The study concluded that, “Despite the rules on transparency and in the particular case of comitology, there seems to be a wide gap between the rules and the practice of disclosing information.”\(^4\)

The committees follow their own rules of procedure, which are generally based on the Standard Rules of Procedure\(^5\) adopted by the Commission in 2001. Article 14 of the Standard Rules of Procedure addresses transparency directly, as it states that the same principles apply concerning public access to the committee’s documents as those applying to Commission documents. However, the Commission takes the decision on whether or not to grant access to these documents. Also, a major hindrance to disclosure can be found in Article 14(2) which states that “The committee’s discussions shall be kept confidential”. This can only serve to undermine the concept of an open and accessible system.

It is precisely this discretion given to the Commission which is one of the key reasons why the comitology procedure is not fully accessible to the public. Examples of deficits in this area include the fact that no notice of upcoming meetings are posted on the comitology website and that the website only posts official meetings and not working group meetings, where many of the key discussions are carried out.

3. ACCESS TO SCIENTIFIC AND TECHNICAL DISCUSSIONS

The Regulation\(^6\) on access to documents of the EU institutions and the Commission’s response to an access to documents request were brought under scrutiny in Cases T-121/05 and T-166/05 Borax Europe Ltd. v Commission.\(^7\) These cases highlight the role that the access to documents regulation plays in shedding light on the decision making process of scientific and technical comitology committees.

In connection with the classification of borates as toxic to reproduction, Borax Europe Ltd (Borax) requested access to documents relating to a key meeting of Specialised Experts on reprotoxicity under the access to documents Regulation. Since Borax considered that the summary record of the meeting did not reproduce either accurately or fully the experts’ statements, comments or conclusions, Borax requested access to:

- All the documents, and more particularly to the entire transcript, unabridged minutes and sound recordings of the meeting. Borax stated that, in the alternative, it would accept partial access to the recordings in the form of written

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\(^4\) Ibid.


\(^7\) Case T 166/05 Borax Europe Ltd v Commission, judgment of 11 March 2009 (not yet published); Case T-121/05 Borax Europe Ltd v Commission, judgment of 11 March 2009 (not yet published).
transcripts, from which the names of persons and countries were deleted (Case T-121/05); and

- Any comments from the experts on the draft summary record of the Specialised Experts meeting and to any documents relating to the classification of perborates (Case T-166/05).

The Commission refused all of Borax’s initial and confirmatory requests arguing that granting access would:

- Undermine the privacy and integrity of the individual experts to the meetings, (Article 4(1)(b) of the Regulation); and,

- Seriously undermine the Commission’s decision-making process, which no overriding public interest would justify (Article 4(3) of the Regulation).

Borax appealed the Commission’s decisions on the confirmatory applications to the Court of First Instance (CFI). The CFI gave judgment in both cases on 11 March 2009.

In both judgments, the CFI started by noting that the purpose of the Regulation is to give the public a right of access to the institutions’ documents which is as wide as possible. This right relates to the democratic nature of those institutions by way of ensuring that decisions are taken openly and closely to the citizens. As such, any exception to the right to access must be interpreted narrowly and applied strictly.

Therefore, the CFI held that if an institution refuses access to a document which it has been asked to disclose, it must explain how access to that document could “specifically and effectivelly undermine the interest protected by an exception” set out in Article 4 of the Regulation and relied on by that institution.

4. THE EFFECT OF EU CASE LAW ON TRANSPARENCY

The CFI also made a number of interesting positive statements, in relation to Cases T-121/05 and T-166/05 Borax Europe Ltd. v Commission, that are likely have broader application in future access to documents cases:

- The legality of a refusal to grant access to a document is to be assessed on the basis of the facts and the law as they stood at the time when the decision was adopted. Therefore, later justifications given, for example, in Court documents are irrelevant.

- The protection of the decision-making process from targeted external pressure may constitute a legitimate ground for restricting access to documents. However, there must be a specific examination of each request for access to documents.

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8 Case T-121/05, paragraphs 31-32; Case T-166/05, paragraphs 38-39.
9 Case T-121/05, paragraph 35; Case T-166/05, paragraph 42.
10 See, to that effect, Case T-121/05, paragraph 37; Case T-166/05, paragraph 44; and Joined Cases C 39/05 P and C 52/05 P Sweden and Turco v Council [2008] ECR I 0000, paragraphs 48 and 49.
11 Case T-121/05, paragraph 48.
• Wider access should be granted to documents in cases where the institutions are
acting in their legislative capacity. In the Borax cases, the opinions expressed in
the written documents and sound recordings in question were obtained for the
purpose of adopting measures classifying the substances concerned. 12

The Court also specifically referred to access to scientific evidence:

• The Commission cannot rely on Article 4(1)(b) of the Regulation to refuse access
on the general ground that disclosure of the identity of experts would result in
them being exposed to undue external pressure that could undermine their
integrity, unless the Commission can show the existence of specific pressure or a
risk of pressure on the part of the company requesting access or on its
initiative. 13

• An argument by the Commission that the contested documents cannot be
disclosed because they contain individual opinions expressed for internal
purposes in a preliminary phase of the final decision conflicts with the very letter
of the second subparagraph of Article 4(3) of the Regulation. That provision, in
fact, expressly allows access to a document containing opinions for internal use
as part of deliberations and preliminary consultations within the institution
concerned. 14

• While there is a specific exception for legal advice, there is no exception for other
types of advice, in particular scientific advice, such as that expressed in the
written documents and sound recordings at issue in the Borax cases. 15

• It follows that scientific opinions obtained by an institution for the purpose of the
preparation of legislation must, as a rule, be disclosed, even if they might give
rise to controversy or deter experts from contributing to the decision-making
process of an institution. This risk is inherent in the principle of public access to
documents. 16

12 Case T-121/05, paragraph 69; Case T-166/05, paragraph 104.
13 Case T-121/05, paragraphs 44; Case T-166/05, paragraphs 51.
14 Case T-121/05, paragraph 66; Case T-166/05, paragraph 101.
15 Case T-121/05, paragraph 68; Case T-166/05, paragraph 103.
16 Case T-121/05, paragraph 70; Case T-166/05, paragraph 105.
5. **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, including a lack of transparency. Without reform these weaknesses pose major challenges for future regulatory quality and for the maintenance of public trust in the legitimacy of EU rule-making.

Although comitology plays a vital role in advising the Commission on legislation and determining the implementation of draft measures, it is important that the procedures followed by the committees are open to public review so as to strengthen accountability. As shown, recent case law has increased access to documents generally and has also laid down rules on providing greater access to scientific and technical evidence.

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This background note 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.