

EU Analyst: Environment & Life Sciences

30 July 2010

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1. NANOTECHNOLOGIES — LATEST DEVELOPMENTS

By [Dr. Anna Gergely](#), [Nancy Russotto](#), and [Tanja Ehnert](#)

Overview

Nanotechnologies are heralded as the basis for the ‘next industrial revolution’, with their commercial use growing exponentially. There are significant knowledge gaps in the understanding of their physico-chemical properties, making it difficult to assess their environmental and toxicological effects. To help foster this technology and fill the knowledge gap, the EU 7th Framework Programme (‘FP7’) established a budget of €3.5 billion for research on nanotechnologies. In this article, we examine the business challenges companies face and introduce [NANO*futures*](#), the EU’s central initiative in this area.

[NANO*futures*: European project on nanotechnologies officially launched](#)

In June 2010, the European Commission and the Spanish EU Presidency officially launched the [NANO*futures*](#) project (as part of the FP7) to bring together industry, research institutions, and NGOs at all levels and co-ordinate their activity. The stated aim is to construct

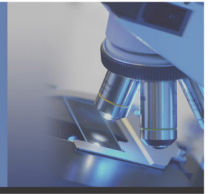
and communicate an integrated industrial and research roadmap for nanotechnologies. Eleven existing European Technology Platforms (‘ETPs’), which are themselves networks co-ordinating regulator and stakeholder activity in particular technological fields, have joined the initiative. The sectors represented by the ETPs include nanomedicine, chemistry, construction, nanoelectronics, nanomanufacturing, transportation, textiles, and photonics.

NANO*futures* is organised into 10 Working Groups, which aim to identify strategies and actions across all industry sectors — a horizontal approach — within their respective field:

- safety research
- industrial safety strategy
- standardisation
- technology transfer and institution financing
- regulation
- industrialisation and manufacturing
- skills and education
- networking
- communication
- research and technology

[Shaping nanotechnologies regulation](#)

Step toe’s nanotechnology practice leader in Brussels, [Dr. Anna Gergely](#), is chair of the NANO*futures* Working Group on Regulation, appointed in recognition of her broad experience in regulatory issues and longstanding work on nanotechnologies. The Working Group will serve as a platform, co-ordinating the regulatory developments for nanotechnologies in the EU. Its role will be to identify the essential elements of a regulatory framework by taking into account all viable regulatory options (voluntary and/or mandatory) as well as the different approaches of the



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industry sectors represented by the ETPs. The Working Group aims to build on industry's stewardship activities, building trust and confidence between industry and regulators and between industry and public.

Since nanotechnologies are enabling technologies, the Working Group on Regulation will adopt a two-tiered approach to address the wide range of affected industries. First, the Working Group will focus on horizontal issues which are of general interest to all sectors. It will compile and analyse past and present regulatory approaches and ongoing initiatives at the EU and national level. Second, the Working Group will focus on specific sectors, channelling and disseminating nanotechnologies-related information provided by the participating ETPs.

A priority will be to establish key regulation "nodes" (critical elements to be reviewed) including (i) a suitable regulatory definition of 'nanomaterial' which could be agreed internationally and (ii) identifying the basis for sector-specific needs.

The first report of the NANOfutures Working Group on Regulation will be published in the first quarter of 2011. In order to guarantee the delivery of a valuable and broadly agreed contribution, the Working Group on Regulation will solicit input from stakeholders.

Preparing for business challenges of emerging regulation

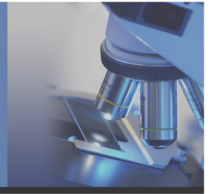
In addition to the NANOfutures initiative, numerous mandatory and voluntary schemes (at national and international level) are underway to provide an appropriate governance framework on nanotechnologies. One of the most recent examples is in France, where a mandatory reporting scheme was adopted as part of the ['Grenelle II'](#) law, which has been presented as France's contribution to supporting the 'green economy'.

Companies have learned from experience the importance of ensuring that the regulatory environment enables them to innovate and bring products to market without undue restriction. Steptoe & Johnson LLP has an integrated team of lawyers and scientists, armed with the knowledge and experience to help companies evaluate compliance of their processes and products with today's regulation (both general and sector-specific) and anticipate the direction of future regulation. In addition to working constructively with the European Commission, we are involved in the work of the OECD and other bodies which are shaping the regulatory environment for nanotechnology-related activities.

Steptoe is providing support to clients with nanomaterials and nanotechnology-enabled products in order to:

- ensure compliance with horizontal (e.g. worker safety) and sector-specific requirements (e.g. REACH);
- protect intellectual property rights;
- manage liabilities and insurance related concerns; and
- effectively influence evolving regulation.

To discuss your needs please contact a member of our nanotechnology team.



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2. COMITOLGY AFTER THE LISBON TREATY

By [Darren Abrahams](#) and [Tanja Ehnert](#)

Overview

Previous editions of EU Analyst have examined how key decisions on EU environment and life sciences regulation are taken behind closed doors. In the EU legal framework, ‘comitology’ committees (made up of a representative from each EU [Member State](#) and chaired by the European Commission) simply implement rules laid down by the [Council](#). However, this is deceptive since their decisions authorise products (e.g. active substances in plant protection and biocidal products and GMOs) and make minor, but commercially significant, amendments to legislation (e.g. the adoption of exemptions to legislation). This has led to a demand for increased transparency and democratic participation.

It is hard to understate the importance of comitology in the formation of EU regulation. In 2009, there were 266 comitology committees in operation. In the 2004-2009 legislative term of the European Parliament (‘Parliament’), these committees completed a total of 447 ‘co-decision’ matters. In contrast, in 2009 alone, comitology committees delivered 2,091 opinions and adopted 1,808 implementing measures. In this article we explain how the Treaty of Lisbon has substantially amended the rules governing how such decisions will be taken in the future. The amended rules will potentially have significant consequences for the balance of power among EU institutions and for stakeholders.

Comitology today: a refresher

Comitology committees today operate under four principal procedures set out in [Council Decision 1999/468/EC](#), with more than half of the committees applying more than one procedure:

- **Advisory procedure:** The committee issues its non-binding opinion (voting by simple majority) on the Commission’s draft measure, which the Commission must take the ‘utmost account of’ before it adopts.
- **Management procedure:** If the committee (voting by qualified majority) agrees with the Commission’s draft measure it is adopted immediately, but if it opposes a draft measure the Commission must refer it to the Council which may adopt a different decision (also voting by qualified majority).
- **Regulatory procedure:** If the committee (voting by qualified majority) opposes the Commission’s draft measure, it must be referred to the Council and the Parliament must be informed. The Council (also voting by qualified majority) may agree to the Commission proposal or oppose it. If it opposes, the Commission will re-examine the proposal and may; (i) amend it for the Council to re-consider; or (ii) re-submit it without amendment; or (iii) present a full legislative proposal. If the Council does not take a decision or achieve a qualified majority for or against, the Commission can adopt it. (The Parliament may inform the Council if it considers that a proposal submitted by the Commission exceeds the Commission’s implementing powers provided for in the underlying legislation, but has no vote or veto. Its sole recourse to protect its prerogatives is to the Court of Justice of the EU.)
- **Regulatory procedure with scrutiny:** This is the [most recent of the procedures](#) (adopted in 2006) and applies two main variants to the regulatory procedure. Firstly, the Parliament may oppose (and thereby veto) the adoption of proposed measures even where the committee agrees with them. It can do this where the draft measures; (i) exceed the implementing powers provided for in underlying legislation; (ii) are not compatible with the aim or content of the basic instrument; or (iii) do not respect the EU principles of subsidiarity or proportionality. Secondly, where a



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proposed measure is vetoed the Commission does not have the option to re-submit it without amendment. Its only alternative is either to submit an amended draft measure or to present a full legislative proposal.

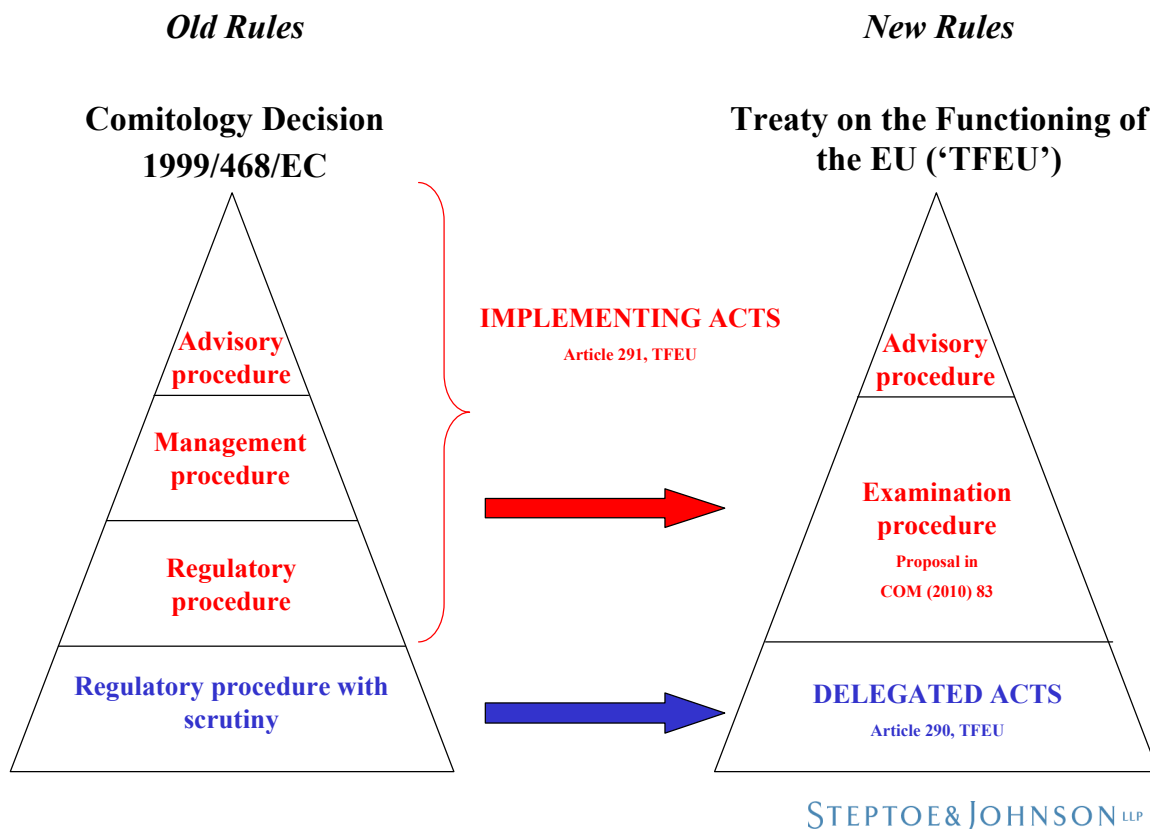
The new regime

The [Treaty on the Functioning of the EU](#) (“TFEU”) establishes two separate (mutually exclusive) procedures that will replace those that currently apply:

- The ‘**delegated act**’ procedure (based on Article 290, TFEU) allows the Commission to adopt ‘non-legislative acts of general application to supplement or amend certain non-essential elements’ of a legislative act. The original legislative act must expressly grant this ‘quasi-legislative’ power to the Commission. The objective of

this procedure appears to be to allow the Commission, exercising its discretion and judgment, to adopt measures to achieve administrative efficiencies. The procedure is likely to be used (but not exclusively) in circumstances where the current regulatory procedure with scrutiny applies.

- The ‘**implementing act**’ procedure (based on Article 291, TFEU) allows the Commission to implement ‘legally binding Union acts’. In doing so, the Commission exercises an ‘executive’ power. The objective of this procedure appears to be to provide the Commission with the power to act to achieve uniform implementation of an act. The procedure is likely to be used in circumstances where the current advisory, management, and regulatory procedures apply.





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Delegated acts procedure

The TFEU does not contemplate adoption of legislation to give effect to this procedure. It is, apparently, self-executing. Nonetheless, the Commission, Parliament, and Council are at present discussing a 'standard formula' process for the adoption of delegated acts. In December 2009, the Commission set out its views on how the procedure should operate in a [Communication](#) and the Council adopted a [Declaration](#). In March 2010, the Parliament set out its views in an own-initiative [report](#) by its Committee on Legal Affairs.

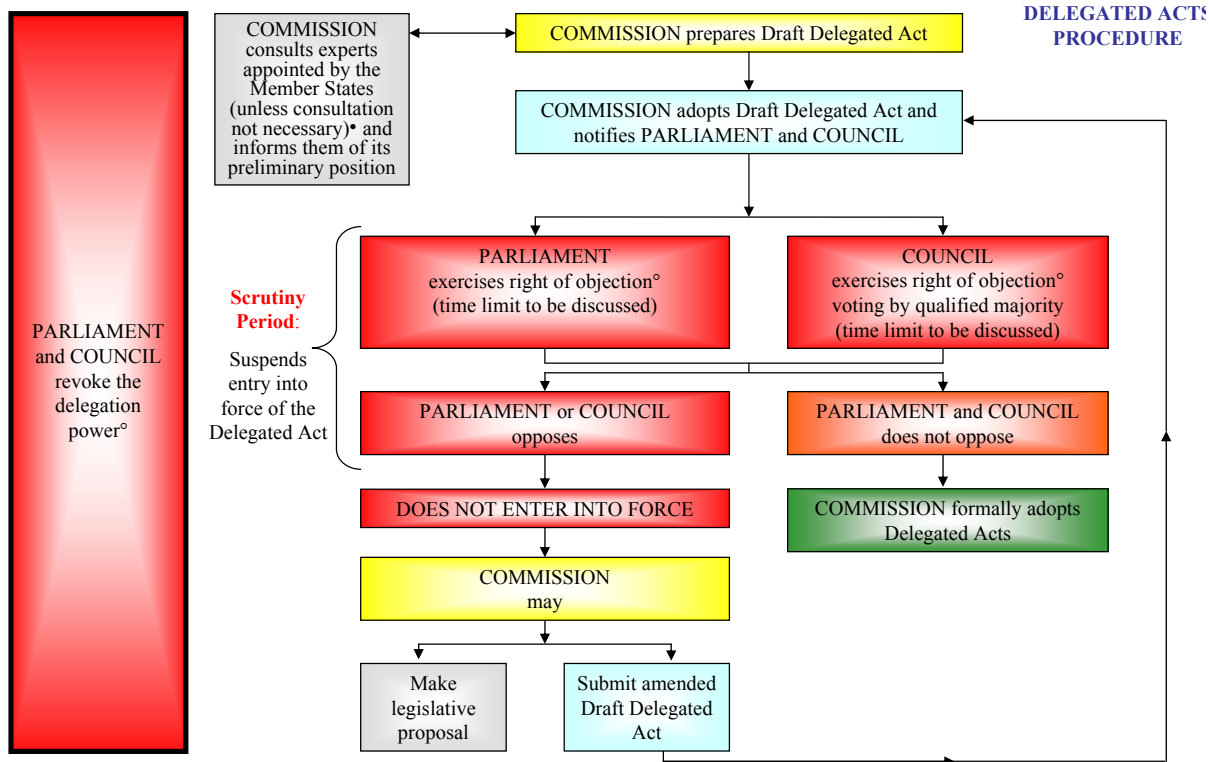
The Parliament is keen to see the practical arrangements for the adoption of delegated acts to be set out in a statement of 'Common Understanding' or some form of interinstitutional agreement. This may be difficult, given that there appears to be disagreement between the Commission and Parliament on two essential issues:

- The delegated acts procedure under the TFEU removes the institutional role of the current comitology committees (which vote on proposals). The Commission does, however, intend to consult Member State representatives 'systematically' (perhaps via existing or new expert groups). This position, which is strongly supported by the Council, will enable it to gather input from those who ultimately will be responsible for the application of delegated acts. The Parliament considers that committees of Member States should 'have no role to play in this area' and entirely rejects the formal consultative role which the Commission proposes. The Parliament's view is that national experts should be treated no more favourably than any other stakeholder who may be consulted.
- The Commission and Parliament disagree on the scope and nature of scrutiny by the Parliament and Council. The TFEU provides for two express mechanisms for

scrutiny by the Council and Parliament: (i) a specific right of objection to delegated acts (likely to be used in most cases); and (ii) a general right to revoke a power of delegation given to the Commission (likely to be used exceptionally). However, the Parliament considers that these two forms of scrutiny are 'purely illustrative' and that other forms of control could be exercised, such as: (i) express approval of each delegated act; or (ii) the ability to repeal individual delegated acts already in force. The two institutions also disagree on the appropriate time limits during which scrutiny can be exercised. The Parliament proposes a case-by-case approach with a minimum scrutiny period of two months, which could be extended by a further two months. The Commission advocates a short, standard time limit of two months, which could be extended by one month.

The diagram on the following page sets out the standard formula as proposed by the Commission.

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* Consultation is required in financial services matters.
 ° Depending on whether the underlying legislative act grants this power.

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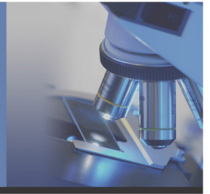
Implementing acts procedure

The TFEU requires the institutions to adopt ‘rules and general principles’ for the operation of this procedure. Accordingly, in March 2010 the Commission issued a [proposal for a Regulation](#) establishing those rules and procedures and repealing the current comitology procedures in [Council Decision 1999/468/EC](#) (which remain in force despite their incompatibility with the TFEU). The institutional role of the current comitology committees, composed solely of Member State representatives, will remain but their decision-making rules will change significantly.

The current advisory procedure (explained above) would become the general procedure for adoption

of implementing acts. The current management and regulatory procedures would be replaced by a new ‘examination procedure’ for ‘implementing measures of general scope’ and other implementing measures relating to: (i) the common agricultural and fisheries policies; (ii) environment, security, and safety or protection of the health or safety of humans, animals, or plants; and (iii) the common commercial policy.

One of the most significant changes under the examination procedure is that, under the Commission’s proposal, neither the Parliament nor Council would continue to play a formal role in the comitology procedure. In May 2010, the Parliament adopted a [draft report](#) on the Commission’s proposal, in which it called for a greater role by both institutions. A further important change



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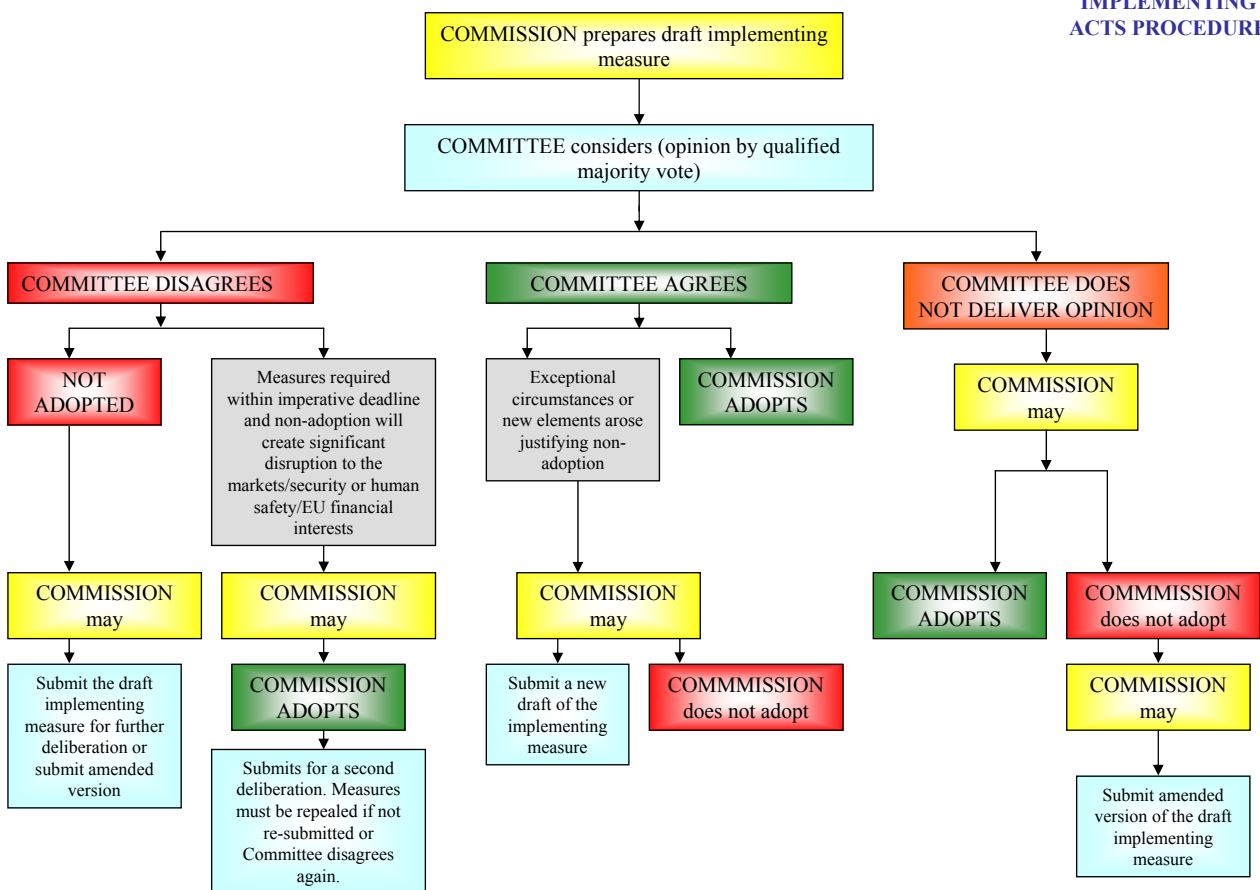
is the increased flexibility given to the Commission in various scenarios. For example, if the committee fails to deliver an opinion within the time limit, the Commission would no longer be forced to adopt a measure but would have the option to do so. This new discretion will be of particular importance in politically sensitive policy areas. The diagram below sets out the new examination procedure as proposed by the Commission.

Next steps

As will be obvious from the above, the transition to the new comitology regime has not been completed. The old

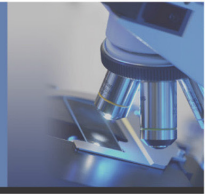
system will apply, at least in part, until the new Regulation establishing the examination procedure enters into force. However, the significant changes outlined above will present challenges for stakeholders hoping to influence their regulatory and business environment. It would be prudent for those concerned, especially in politically sensitive product sectors, to make their views known during the legislative passage which will lead to the adoption of the new examination procedure. They should also monitor the current debate in order to ensure that they fully understand and can participate in the new comitology procedures in the form ultimately adopted.

IMPLEMENTING ACTS PROCEDURE



Proposal in COM (2010) 83

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To review previous editions of the EU Analyst, please [click here](#).

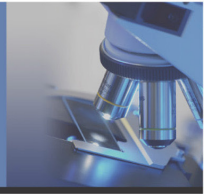
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