EUROPEAN RISK FORUM – POLICY NOTE 28

THE EUROPEAN COMMISSION CHIEF SCIENTIFIC ADVISER – "BUILDING FOR THE FUTURE"

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EXECUTIVE SUMMARY

The decision by President Barroso to appoint a Chief Scientific Adviser represents an important opportunity to build on successful reforms carried out by the European Commission, and to create the institutional architecture needed to ensure that high quality scientific evidence is used effectively to improve further the quality of EU-level legislative and regulatory decisions. The organisational role, responsibilities and resources allocated to the Commission's new Chief Scientific Adviser should recognise the contribution that good scientific advice makes to improving regulatory quality and, in turn, to delivering the EU's Better Regulation goals.

During its relatively short life the office of the Chief Scientific Adviser (CSA) has made a considerable and positive difference to the regulatory environment at EU-level. Action is needed to embed this improvement into the institutional structures of the European Commission.

In view of this, it is recommended that:

- The post of Chief Scientific Adviser (CSA) should become a permanent part of the European Commission's organisation;
- The Commission's CSA should report directly to the President of the European Commission and should be responsible for ensuring the integrity, quality and effective operation of the scientific advisory system;
- The position of CSA should be at a level equivalent to that of a Director-General of the European Commission;
- The European Commission should establish a central unit in support of the CSA, and allocate appropriate resources to it for the fulfilment of the CSA mandate;
- A steering group, chaired by the CSA, should be established to oversee and co-ordinate the use of science by the Commission, its agencies, and its Technical Working Groups;
- The Joint Research Centre should provide expertise and administrative support to the network of science advisors.
- A network of senior scientific advisers should be established located in each DG and relevant Cabinet;
- The Joint Research Centre should provide expertise and administrative support to the network of science advisors;
- The CSA should become a member of the Impact Assessment Board;
- The CSA should establish a new, coherent policy for the collection and use of scientific advice;
- A formal policy for managing risks posed by new technologies should be drawn up by the CSA;
- A policy for improving public acceptance of the use of scientific evidence in decision-making should be drawn up and implemented by the CSA;
- The CSA should develop and publish mandatory written principles that define the quality and relevance of studies, information, and data to be used in scientific assessments by the European Commission's scientific advisers and committees;

- The CSA should require significant risk assessment opinions to be independently peer-reviewed;
- Mandatory guidelines for the presentation of scientific advice to risk managers and policy-makers ("internal risk communication") should be drawn up by CSA;
- The review of legislation based on the Precautionary Principle on which the initial scientific uncertainties were dispelled by new research and wide scale experience.
- The CSA should promote and coordinate a network of equivalent institutions at Member State level and maintain close contacts with national and international standards bodies and scientific institutes so that best science is applied in the EU.

1. BACKGROUND

In managing a wide range of risks to the environment, public safety, and human health in most modern economies, scientific evidence is the key knowledge input for decision-making in all stages of the 'regulatory cycle'. Used well, science provides effective ways of identifying potential risks, protecting citizens, and using resources wisely. It enables government decisions to be based on evidence derived from transparent, rational processes designed to enhance legitimacy and trust. Moreover, it provides theories with explanatory and predictive power, enabling policy-makers to anticipate problems and to develop effective solutions.

Most scientific evidence is provided to policy-makers and decision-makers through a process of 'scientific assessment'. This involves an expert assessment of the state of knowledge, and the implications of 'known' scientific evidence. At EU-level, these assessments are increasingly undertaken by scientific committees established on the basis of 'independence' and 'excellence'.

There is, however, an emerging debate as to the appropriate role of scientific evidence in determining the outcome of legislative and regulatory decisions. This has been caused by rising concerns about the limitations of science and the increased importance of 'non-scientific' factors, including social concern and risk perception.

Hence, a challenge facing all governments is to ensure that good science retains its central role in policy-making and decision-making processes, whilst taking appropriate account of the structural limitations of scientific evidence and the increasing importance of non-scientific factors.

During the period of the Barroso presidency, the EU institutions have taken steps to strengthen the impact of high quality science on decision-making. A European Science and Technology Council (EASAC) has been established. New, binding Rules of Procedure have been agreed for the Commission's three independent scientific committees. Amongst other changes they now recognise the unacceptability of bias in scientific advice; they emphasise the importance of the quantification of risk assessment and of meeting international standards; and, they require risk assessments to be based on the best available evidence and for criteria used for evaluating data and scientific information to be explained. In the European Parliament, a Working group on Risk has been set up, chaired by Julie Girling MEP. To provide scientific support MEPs, a new Impact Assessment Directorate has been established, encompassing STOA. Finally, the Commission has appointed a Chief Scientific Adviser, Professor Anne Glover, reporting directly to President Barroso.

Taken together these are important reforms. Despite this, more needs to be done. On too many occasions in the recent past, poor quality scientific evidence has informed policy-making, creating costs without benefits, failing to improve protection of citizens, and weakening incentives to innovate. The institutional architecture, policies, and procedures needed to build on these reforms remains, moreover, incomplete. Indeed, the post of Chief Scientific Adviser has yet to be institutionalised within the Commission.

This ERF Policy Note focuses on the future development of the role of the Chief Scientific Adviser. It highlights what has been achieved so far, assesses future challenges, and identifies recommendations for action.

2. CHIEF SCIENTIFIC ADVISER – BENEFITS

During its relatively short life the office of the Chief Scientific Adviser (CSA) has made a considerable and positive difference to the regulatory environment at EU-level. The office has become:

- **A public champion of the importance of basing regulatory decisions on high quality science**- the CSA has up-held the importance of the scientific method, criticising the poor quality of research used to stigmatise some technologies. The need to base policy and regulatory decisions on the best available science, regardless of its origin, has also been highlighted by the CSA, along with the need to be alert to the possible bias of research generated by activist campaigning scientists.

- **A promoter of balance and rationality in controversial debates** – in areas such as the safety of GMOs, development of shale gas, and the regulation of endocrine disrupting substances, the CSA has enhanced public discourse by countering the arguments based on poor science and perceived risk. This contributes to insert balance into policy and regulatory debates, thereby enhancing the quality of risk communication within the EU institutions and increasing the quality decision-making over time.

- **A symbol to citizens, businesses, and trading partners that policy in the EU will be predictable and based on high quality, internationally-accepted science** – by creating the office of CSA, the European Commission has made a clear statement to the citizens of Europe, investors, and trading partners. It states that science will underpin laws to protect citizens and the environment, delivering genuine net benefits to society. Within this context, a more predictable regulatory environment should emerge, reducing trade frictions and removing obstacles to investment in innovation. The appointment of the CSA contributes to current trade negotiations by strengthening the role of science and hence facilitating regulatory convergence.

- **A formal institutional mechanism for dialogue between the Commission and stakeholders, whenever there are concerns about the role of science in decision-making** – by this reform, a gap in the institutional architecture of the EU has been closed and Smart Regulation promoted. Opportunities for public participation in decision-making have been strengthened; a core requirement of good administration.

- **A formal institutional mechanism to ensure that 'science' has a voice in policy-making** – this change helps to improve balance in policy-making, as well as providing a means of ensuring that the quality of evidence used to justify government action is subject to robust challenge and review.

- **A leader of cross-agency dialogue** – the office of the CSA has set a committee of agency scientific advisers, beginning the process of creating networks of experts across the Commission. This builds on earlier work undertaken by the chairs of the independent scientific committees to enhance their Rules of Procedure. The role of the CSA as a leader of dialogue between scientific advisers also encompasses links with the chief scientific advisers in Member States. Eleven of the Member States have such positions.

- **Facilitator of links between European Academies Science Advisory Council (EASAC) and the Commission** – contacts have been made between key Directors'-General and EASAC, as a result work undertaken by the office of the CSA.

- **A promoter of new thinking on how organise the early stages of policy formulation** – the office of the CSA has, for instance, produced ideas on the interface between science, roadmaps, impact assessments and public consultation.

These are major improvements and action is needed to embed them into the institutional structures of the European Commission.

3. CHALLENGES

At EU-level, the process of developing the policies, procedures, and institutions needed to ensure that risk management decisions are based on high quality science is incomplete. Indeed, reformers within the EU's institutions must overcome a number of challenges, if they are to build a robust approach for the future. These challenges include:

- **Creating an institutionalised structure for the CSA** – at present, the post of the CSA is not formally part of the European Commission's permanent organisation. Moreover, the CSA Office is manifestly under-resourced. Future presidents of the commission have the discretion to decide whether or not to continue with the post. Failure to reconfirm the post and equip the office appropriately would send a strong signal the EU was not committed to using high quality science to regulate risk: it would undermine the confidence of business and trading partners, without delivering any improvement in the protection of citizens or the environment.

- **Ensuring a stronger presence of scientists in decision-making processes throughout all parts of the Commission** – this requires the creation of a deep institutional network and privileged access to key policy processes, including ex ante impact assessment.

- **Developing world-leading policies and processes for the use of science in decision-making** – there a number of gaps in the EU's approach, including lack of modern, Commission-wide policies for risk governance and information quality (including requirements for scientific evidence, international consensus on evidence, and peer review of risk assessments)

- **Reducing the number of poor quality risk management decisions** – despite the general commitments of the Commission to take proper account of science, the outcomes of too many controversial risk management decisions continue to be inappropriately influence by either poor quality science or partial (hazard-based) approaches, or again special minority interest groups.

- **Preventing the loss of access to high quality scientific expertise** – this has occurred because of the way in which the EU's policies for providing scientific advice are increasingly implemented. EU policy requires advice to be 'independent', and 'excellent'. But all too often officials, charged with securing scientific advice, deem the requirements of 'independence' and 'excellence' to be satisfied, if evidence and advice are supplied solely by scientists from academia (or equivalent). Whilst this appears to be a practical solution, it can have the effect of preventing decision-makers from gaining appropriate access to the scientific expertise of the private sector. In turn, this lack of access to cutting edge of new science makes it difficult for governments to manage harms well.

4. RECOMMENDATIONS

The decision by President Barroso to appoint a Chief Scientific Adviser represents an important opportunity to build on successful reforms carried out by the European Commission, and to create the institutional architecture needed to ensure that high quality scientific evidence is used effectively to improve further the quality of EU-level legislative and regulatory decisions. The organisational role, responsibilities and resources allocated to the Commission's new Chief Scientific Adviser should recognise the contribution that good scientific advice makes to improving regulatory quality and, in turn, to delivering the EU's Better Regulation goals. In view of this, it is recommended that:

- **The post of Chief Scientific Adviser should become a permanent part of the European Commission's organisation.** This will ensure continuity, remove uncertainty and allow pursuing the Commission efforts at ever higher quality regulatory decisions.

- **The Commission's Chief Scientific Adviser should report directly to the President of the European Commission and should be responsible for ensuring the integrity, quality and effective operation of the scientific advisory system.**

- **The position of Chief Scientific Adviser should be at a level equivalent to that of a Director-General of the European Commission.** This will strengthen the importance and legitimacy of the role.

- **The European Commission should establish a central unit in support of the Chief Scientific Adviser, and allocate appropriate resources to it for the fulfilment of the CSA mandate.**
  - Developing the overall scientific advice policy and the specific guidelines that underpin the operation of the entire advisory system, including Technical Working Groups, Risk Assessment Agencies, and the Commission's independent scientific committees;
  - Providing additional expert resources, advice and support to Scientific Advisory Committees and officials;
  - Enforcing compliance with common guidelines; with the aim to weed out junk science
  - Auditing the extent to which science is used effectively in policy-making and decision-making processes;
  - Commissioning periodic external evaluations of the operation of the overall scientific advisory system;
  - Producing an annual review of the effectiveness of the scientific advisory system

- **A steering group, chaired by the Chief Scientific Adviser, should be established to oversee and co-ordinate the use of science by the Commission, its agencies, and its Technical Working Groups.** This group should focus on improving the quality, credibility, and utility of scientific evidence used by Commission Services and EU-level risk assessment agencies and Technical Working Groups to support policy-making, secondary legislation and regulatory decisions (including case-by-case adjudications, guidelines, and rule-making).

- **The Joint Research Centre should provide expertise and administrative support to the network of science advisors.** Where expertise of the basis of evidence is missing or incomplete within DGs, the network of science advisors can draw upon assistance from the JRC.

- **A network of senior scientific advisers should be established located in each DG and relevant Cabinet.** All appointments should be approved by the Chief Scientific Adviser to ensure that only suitable staff are selected. These advisers will be the defenders of evidence-based policy-making and of the scientific method. The CSA should chair the network.

- **The Chief Scientific Adviser should become a member of the Impact Assessment Board**, with specific responsibility for assessing the quality of scientific evidence used to justify regulatory action and for reviewing all risk management decisions which make use of the Precautionary Principle.

- **The Chief Scientific Adviser should establish a new, coherent policy for the collection and use of scientific advice.** The policy should be applied to all stages of the regulatory cycle and to all sources of scientific advice, including formal Scientific Advisory Committees, Risk Assessment Agencies, Technical Working Groups, Comitology Committees (and equivalent bodies set up to implement legislation using the new mechanisms set out in the Lisbon Treaty), and other bodies such as EEA. The policy statement should:
  - Define a set of guiding principles for the collection, assessment and provision of scientific advice. These principles should have a presumption favouring peer reviewed data and results and require sufficient transparency to facilitate reproducibility. They should also require studies, information, and data to be based on widely accepted and objective practices (the “scientific method” and peer review);
  - Require legislative and regulatory decisions to be based on the best available science;
  - Emphasise the paramount importance of ‘excellence’ and define ‘independence’ on the basis of objectivity. This should define tests of objectivity that encompass both ‘bias’ and conflict-of-interest’; it should recognise the need to gain access to all sources of expertise, including that funded by the private sector; and it should require studies and data to be assessed solely on the basis of scientific quality.
  - Describe clearly the benefits and limitations of using scientific evidence to manage risks to human health and the environment; and
  - Provide a comprehensive set of key concepts and definitions used in the provision of scientific advice, including definitions of ‘best available science’, the ‘scientific method’, ‘uncertainty’, ‘hazard’ and ‘risk’.

- **A formal policy for managing risks posed by new technologies should be drawn up by the Chief Scientific Adviser.** This should highlight the important role that well-designed regulation, based on high quality science, can play in supporting innovation. It should, moreover, require risk management legislation to be technologically-neutral and should recognise the negative consequences for citizens of stigmatising new ideas (or products), and locking-in old technologies;

- **A policy for improving public acceptance of the use of scientific evidence in regulatory and legislative decision-making should be drawn up and implemented by the Chief Scientific Adviser.** This should emphasise the role of high quality science in identifying significant risks and in developing effective risk management outcomes. It should also highlight the link between the EU's Better Regulation goals and the use of high quality science as the key knowledge input for risk management decisions.

- **The Chief Scientific Adviser should develop and publish mandatory written principles that define the quality and relevance of studies, information, and data to be used in scientific assessments by the European Commission's scientific advisers and committees** (including EU-level risk assessment agencies, Technical Working Groups, and Rapporteur Member States). 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. Appropriate guidance should also be developed to ensure effective and consistent implementation. Guidance should encompass all forms of scientific evidence including epidemiological studies and animal testing.

- **The Chief Scientific Adviser should require significant risk assessment opinions to be independently peer-reviewed**, strengthening the processes used to collect and review scientific evidence. Use of peer review should be limited to findings from reviews by scientific advisers, which are likely to have a substantial impact on public policy or the decisions of private companies or the freedoms of citizens.

- **Mandatory guidelines for the presentation of scientific advice to risk managers and policy-makers ("internal risk communication") should be drawn up by Chief Scientific Adviser.** These should, for example, require written explanations explaining conclusions, particularly with regard to the acceptance or applicability of specific studies and findings, and explaining why some studies were not considered or some findings were rejected.

- **The CSA should promote the review of legislation which was based on the Precautionary Principle**, in which the initial scientific uncertainties have been subsequently dispelled as a result of new research and wide scale experience.

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This Policy Note was written by Richard Meads, the European Risk Forum's Rapporteur. However, the views and opinions expressed in this paper 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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