Better Risk Regulation Governance for a Stronger Europe

The Institutionalisation of the EU Chief Scientific Adviser Office

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The start of a new European Commission represents a unique opportunity to build on successful regulatory reforms and to create the institutional architecture needed to ensure that high quality scientific evidence is used effectively in EU decision-making. The appointment by President Barroso of a Chief Scientific Adviser (CSA) in 2011 constituted an important springboard in this respect. The CSA Office has made a considerable and positive difference to the regulatory environment. This article argues for embedding the CSA Office into the institutional and procedural arrangements of the Commission by re-defining its organisational role and responsibilities as well as the resources allocated to it. The institutionalisation of the CSA Office and the creation of a fully-fledged risk regulation regime would provide a robust element of the EU’s response to the demands for better governance by its citizens, as expressed in the recent European elections.

I. Introduction

EU citizens have made their views clear in the past European elections. Without significant reform, the EU institutions face a crisis of legitimacy. Changes are needed in the scope of activity, policy goals, and in the way in which decisions are made. Indeed, reforms of governance must be undertaken to improve EU decision-making so that more emphasis is placed upon promoting inclusive and sustainable innovation and growth rather than accommodating volatile and, on too many occasions, ill-founded social concerns. One key element of the EU’s response should lie in demonstrating that decisions by the EU institutions are based on a thorough scientific and socio-economic assessment and are supported by open consultation, instead of being driven by administrative discretion, politics and poor evidence.

Improved public management of harms (so-called “risk regulation”) helps re-build the trust of citizens in the legitimacy of EU institutions. It is a core function of modern government. It protects citizens and the environment from potential threats posed by technologies and life-style choices. In the EU, it is also a pre-condition for the functioning of the internal market. And, because of its scale and pervasiveness in both public and individual spheres, it plays a paramount role in societal well-being.

1. The role of science in modern government

Scientific evidence is the key knowledge input for decision-making in all stages of the “regulatory cycle”, when it comes to managing risks to human health, public safety and the environment. 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, enhancing 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 undertaken by agencies and 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 concerns and risk perception; as well as by the priority given to hazard-based considerations.

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 legitimate factors.

2. The importance of governance

Good governance of risk regulation is important for the future of the EU. Measures taken to manage harms are often controversial, visibly involving the EU directly in the lives of citizens and consumers. In this context, good decision-making, based on credible evidence, constrained by the rule of law, and based on transparent processes, is essential for legitimacy and to maintain public trust in the EU.

Over the past years, the EU institutions have taken organisational and procedural 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 (from all sources) 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, under the leadership of Julie Girling MEP. To provide scientific support to MEPs, a new Directorate for Impact Assessment and European Added-Value has been established, encompassing the Science and Technology Options Assessment unit (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. Social concerns have been accorded greater importance than science; decision-making processes have been opaque; risk aversion has been preferred to risk acceptance; and the likelihood of harm has been ignored, focusing instead on hazard.

This article 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 as identified by the European Risk Forum to complete the EU risk regulation governance.

II. Current Challenges in the EU Risk Regulation Governance

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.

A first set of challenges refers to systematically developing world-leading policies and processes for the use of science in decision making. The EU is called upon to meet ever higher safety standards but it lacks 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). As a result, the outcomes of too many controversial risk management decisions continue to be inappropriately influenced by poor quality science.
or by partial (hazard-based) approaches, or, as happens too often at EU level, by special minority interest groups.¹

Further challenges relate to the type of scientific evidence collected, validated and used. Full access to high quality scientific expertise is often jeopardised 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 fails to recognise that a substantial number of scientists pursue activist agendas, focusing shaping results to fit pre-determined ideological goals rather than adhering to the demand of the scientific method. Outcomes are as a result biased and should play no part in informing policy-making. Of equal importance, the focus solely on academia 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 understand harms fully or to manage them well.²

Finally, the post of the CSA is not formally part of the 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. Similarly, the presence of scientists in decision-making processes throughout all parts of the Commission is still unsystematic.

III. Benefits from the Chief Scientific Adviser action

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 upheld 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.³

- 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 other arguments based on poor science and perceived risk. This contributes to inserting balance into policy and regulatory debates, thereby enhancing the quality of risk communication within the EU institutions and, over time, increasing the quality of decision-making.⁴

- 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 CSA Office, the Commission has made a clear statement to the citizens of Europe, investors, and trading partners. It states that the highest quality 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

¹ This issue has been highlighted in a series of ERF meetings over the past decade and encompasses sectors such as metals, pharmaceuticals, specialty chemicals, consumer products, and agriculture.

² Certainly a good practice in this respect is the initiative by the European Food Safety Authority (EFSA) to open some of its plenary meetings to “observers”, i.e. interested individuals who can observe how risk assessment is conducted by EFSA’s Scientific Committee and its Scientific Panels, and at the same time interact with and put questions to EFSA’s scientific experts. See http://www.efsa.europa.eu/en/stakeholders/observers.htm.

³ Prof. Glover has addressed these issues at ERF events and in several of her public speeches.

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\(^5\) 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 up 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 (or equivalent) positions.

- Facilitator of links between European Academies Science Advisory Council (EASAC) and the Commission – Contacts have been made between key Directors-General as well as with EASAC\(^6\), as a result work undertaken by the office of the CSA.

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

These are major improvements. Failure to reconfirm and upgrade the CSA mandate as a permanent part of the European Commission may significantly jeopardise them.

IV. Recommendations

The 2012 decision by President Barroso to appoint a Chief Scientific Adviser represents an important opportunity to build on successful reforms. To continue along the reform path, the organisational role, responsibilities and resources allocated to the CSA Office should recognise the contribution that good scientific advice makes to improving regulatory quality and, in turn, to delivering the EU’s Smart Regulation goals. Failure to reconfirm the CSA post and equip the office appropriately would send a strong signal that 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.

The start of a new European Commission represents a unique opportunity to build on successful regulatory reforms and to create the institutional architecture needed to ensure that high quality scientific evidence is used effectively in EU decision-making. The ERF considers the institutionalisation of the CSA Office as the pivotal element around which to improve the whole risk regulation governance within the Commission.

This implies a series of inter-related steps that have organisational, procedural and methodological consequences. Five main recommendations are likely to bring about the envisaged new system:

(1) 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 the Commission to deliver ever higher quality regulatory decisions. The EU CSA should continue reporting 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.

(2) The mandate of the CSA should be upgraded and encompass:

- Developing and enforcing 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;
- Auditing the extent to which science is used effectively in policy-making and decision-making processes;

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– Commissioning periodic external evaluations of the operation of the overall scientific advisory system; and
– Producing an annual review of the effectiveness of the scientific advisory system.

3 The Commission should establish a central unit in support of the CSA, and allocate appropriate resources to it for the fulfilment of the CSA mandate. 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.

4 The direct role of the CSA in the Commission decision-making should be strengthened. To that end:
– A Steering Group, chaired by the CSA, should be established to oversee and coordinate 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);
– A network of senior scientific advisers should be established located in each DG and relevant Cabinet. All appointments should be approved by the CSA to ensure that only suitable staff is selected. These advisers will be the defenders of evidence-based policy-making and of the scientific method. The CSA should chair the network;
– The CSA 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 CSA should require significant risk assessment opinions to be independently peer-reviewed, strengthening the processes used to collect and review scientific evidence; and
– The CSA should promote a review of precautionary measures, in which the initial scientific uncertainties have been subsequently dispelled as a result of new research and wide scale experience.

5 The CSA should be made responsible for establishing and implementing a new, coherent set of risk governance policies to be applied to all stages of the regulatory cycle and to all sources of scientific advice. The policy set should cover:
– the collection and use of scientific advice;
– improving public acceptance of the use of scientific evidence in regulatory and legislative decision-making;
– determining the quality and relevance of studies, information, and data to be used in scientific assessments; and
– presenting scientific advice to risk managers and policy-makers (“internal risk communication”).