Better Use of Science for Better EU Regulation

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Risk regulation is a major task of the EU. In this context, scientific knowledge and advice is critical to the preparation, formulation, legislation and later revision of EU risk regulation. However and with some notable exceptions (e.g. some EU Agencies, DG SANCO), there seems to be no systematic view, let alone, organisation for the 'use of science' for EU policy-making. It is in this light that the new function of Chief Scientific Advisor (CSA) to the President of the European Commission can best be appreciated. The authors first sketch how 'science' is used in the EU regulatory regime and what is or has become problematic about it. Subsequently, an informal SWOT analysis of the 'use of science' for EU policy is conducted. The contribution ends with an attempt to evaluate the CSA's accomplishments to date and how it can contribute to improving EU regulation. This is followed by a few recommendations on how the role of the CSA could be strengthened in the near future.

I. Background and purpose[1]

Risk regulation is a major task of the EU if not its 'core business', given the importance of the EU internal market for what the EU does. Indeed, most EU regulation is actually risk regulation.[2] In this context, scientific knowledge[3] and advice is critical to the preparation, formulation, legislation and later revision of EU risk regulation.[4] Risk regulation is based on risk assessment, which is and can only be the domain of scientists, ensuring full respect of scientific methods and demanding requirements for assessing risks. Also the migration from scientific risk assessment to its use in the Commission's Impact Assessment of proposed new or amended legislation and subsequently for decision-making on EU risk regulation, requires scientific advice. Moreover, scientific knowledge may play a role in risk management too, when technical specifications are decisive in EU regulation, or when new research may call for revisions of existing rules. Finally, science might be of help in risk communication. Besides, there is the vexed problem of deciding whether or not there is 'sufficient' scientific evidence for a risk assessment with reasonably firm conclusions, quantitative and /or qualitative. If not, this may trigger the application of the precautionary principle.

Yet, there is no clear EU system for the 'use of science' for EU regulation and policy-making. In what follows, 'using science' is broadly defined as transferring the results of scientific research to policy-making.[5] In this respect it is important to stress that this article is not about the quality of science; in other words, it does not aim at establishing what 'good science' is.[6] Rather, the analysis starts from the point where scientific knowledge is transferred/used in

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1 The authors are indebted to the referee for critical, useful comments. The considerable revision from an earlier draft is largely inspired by these comments.

2 A good practical definition of its scope is all regulation for Safety, Health, Environment, Investor (and savers') and Consumer protection (SHEIC), including 'systemic risks' in such areas. Note that SHEIC is not exhaustive (e.g. risks connected with terrorism, crime), but this will be ignored here.

3 The terms 'science' and 'scientific knowledge' are used interchangeably in this contribution.

4 For the definition of EU risk regulation, see section II.

5 Note that we will not delve into the complexity of the use/role of science in policy-making. On this point and in general on the use/misuse of academic knowledge in policy debates see i.a. Frank Heller (ed.) *The use and abuse of social science*, (Sage, 1986). Julia Hertin et al., "Rationalising the policy mess? Ex ante policy assessment and the utilisation of knowledge in the policy process", 41 *Environment and Planning A* (2009), pp. 1185 *et sqq.*; W. Henry Lambright, "Government and science: a troubled, critical relationship and what can be done about it", *Public Administration Review* (2008), pp. 1 *et sqq.*; Eric Montpetit, "Scientific credibility, disagreement, and error costs in 17 biotechnology policy subsystems", 39 *Policy Studies Journal* (2011), pp. 513 *et sqq.*; Lorna Schrefler, "The usage of scientific knowledge by independent regulatory agencies", 23 *Governance* (2010), pp. 309 *et sqq.*; Carol H. Weiss, "The many meanings of research utilization", 39 *Public Administration Review* (1979), pp. 426 *et sqq.*

6 This, the authors believe, is best left to the members of the various disciplines that are relevant for EU regulation and policy-making.

policy-making. Indeed, as we will explain in greater detail below, this is where the new function of Chief Scientific Advisor (CSA) to the President of the European Commission can best be appreciated. In particular, we wish to explore how this function has and/or can contribute to the improvement of EU regulation via a better use of scientific knowledge in policy-making. After all, the rationale for adding this specific function to the overall EU governance structure was part of a broader set of commitments to smart regulation[7] put forward by President Barroso at the start of his second mandate.[8]

The EU disposes of four important and competent EU Agencies – EMA (medicines), ECHA (chemicals), EFSA (food and feed) and ECDC (European Centre for Disease Prevention and Control) – which function largely as risk assessment bodies with great expertise in-house and many scientific committees with independent scientists. In addition, the Joint Research Centre (with some 2500 scientists in various areas) serves as an in-house reservoir of expertise and knowledge that the European Commission taps very frequently. DG SANCO enjoys the critical services of the Committees on Health and Environmental Risks (SCHER), on Emerging and Newly Identified Health Risks (SCENIHR) and on Consumer Safety (SCCS). However there would seem to be no systematic view, let alone, organisation, for the 'use of science' for EU policy-making. The Commission has developed, and employs on a daily basis, guidelines for impact assessment – from 2009 and due to be revised in 2014 - but does not have dedicated guidelines on risk assessment. Neither the Commission, and its many policy officials, nor the other leading EU bodies can be expected to be fully capable of handling the 'use of science' properly without well-thought-out guidelines on the interpretation and the pitfalls of migrating scientific knowledge to input for EU policies and rules in a transparent and responsible fashion.

The impact assessment process remains, together with other better/smart regulation tools such as public consultation, the most codified (i.e. established) way of using (scientific) knowledge for policy-making purposes at the EU level. In this light, it offers a valuable perspective/angle to comment on the role of a CSA in the overall system of EU regulation and policy-making. Indeed, in most cases, the 'use of science' in this system is all about the risks. Hence, while the core of our argument naturally focuses on risk regulation, the broader better/smart regulation context of which it is part serves as the overall framework for our analysis.

The present contribution consists of a brief reminder (given space constraints) of how scientific knowledge is used for EU regulation, as a background for a tentative appreciation of the new CSA function insofar as this is possible after the barely two-and-a-half-years that it exists. The latter discussion will be divided in two steps. First, an informal SWOT analysis of the 'use of science' for EU risk regulation will be presented. Based on that analysis, we attempt to evaluate the accomplishments to date. We show that the new function has already generated value-added in the EU organization for promoting 'better EU regulation' and conclude with some recommendations on how the function of the CSA could be strengthened.

II. Using science for EU risk regulation

It is not so easy to understand how the EU policy-making system makes 'use of science'.[9] Of course, an appreciation of how science is used (or underused, misused or ignored) in the EU regulatory regime is indispensable in order to understand the context and background of the appointment of a CSA so high in the hierarchy of the European Commission. In the

7 On recent developments in the EU's approach to better/smart regulation, Communication from the Commission: "Smart Regulation in the European Union" COM(2010)543; and Communication from the Commission, "EU Regulatory Fitness", COM(2012)746. For in depth-analysis of the topic, see i.a. Anne C. Meuwese, *Impact Assessment in EU Law-Making*, (Alphen aan den Rijn: Kluwer Law International, 2008).

8 The second Barroso mandate runs from 2009 to 2014. For further details, see Speech 09/391 of Jose Manuel Barroso, *Passion and responsibility: strengthening Europe in a time of change*, European Parliament Plenary, Strasbourg, 15 September (2009), available on the Internet athttp://europa.eu/rapid/press-release_SPEECH-09-391_en.htm. Press release on the appointment of the first CSA on December 5, 2011, available on the Internet at: http://europa.eu/rapid/press-release_IP-11-1497_en.htm.The actual appointment of the first CSA (Professor Anne Glover, a biologist) only occurred two years later in December 2011. For further details, see e.g. "EU's overdue chief scientist to be appointed this year", Nature News Blog, 7 February 2011, available at: http://blogs.nature.com/news/2011/02/eu_gives_itself_three_years_to.html (last accessed September 2014).

9 For one of the few empirical contributions on the topic, see Dovilė Rimkutė and Markus Haverland, "How does the European Commission use scientific expertise? Results from a survey of scientific members of the Commission's expert committees", *Comparative European Politics* (2014), available on the Internet at: http://www.palgrave-journals.com/cep/journal/vaop/ncurrent/index.html#27012014.

following we first sketch the orthodoxy of 'using science' for the purpose of EU risk regulation. Subsequently, some major issues with this orthodoxy will be set out and some of these will be echoed in the SWOT analysis in section III. We conclude with two examples to illustrate why science matters for EU policy-making.

1. Using science for risk regulation: How is it done and what is problematic?

The classical rationale for risk (or any other type of) regulation is the presence of market failures. Given the imperative of the EU internal market, such risk regulation will have to be enacted at the EU level unless mutual recognition can deal with it properly.[10] In making (EU) risk regulation, the risk(s) is (are) first identified; once this is done, a political judgment has to be made whether the EU finds that risk acceptable; if not, EU regulation is expected to reduce the risk to a tolerable level, given costs and benefits and possible indirect implications (such as induced changes in company or consumer conduct, induced by the proposed regulation, leading to new risks). The benefit of such EU risk regulation amounts to the risk reduction accomplished, which can be quantified under some restrictive assumptions, but is usually complemented by qualitative considerations. The costs of EU risk regulation consist of resources spent on compliance by companies and consumers/citizens, including adaptations of the production process, and/or the development of new technology, but also the administrative costs of documentation and information provision to authorities. The European Commission's Impact Assessment (IA), with careful and detailed procedures, is meant to provide the full policy and empirical (economic, environmental and social) impact analysis, with a range of policy options, to underpin 'better EU regulation'. The EU legislator is expected to make wise use of such Impact Assessments but of course remains free to decide, given their accountability to voters. Accountability is best served if EU decision-makers make explicit where and why they use the IA and where and why not.

As mentioned, using science in this system is all about the risks. Politicians and (EU and national) officials are not equipped to establish the risks and the underlying scientific knowledge (state of the art). This should be left to scientists. Mixing up the two can lead to 'bad science' and 'bad regulation'. Therefore, since a few decades, the simple but elegant orthodoxy has it that three core functions in risk regulation ought to be separated for reasons of expertise and of responsibility: risk assessment for 'science', risk management deciding politically on what risk reduction is tolerable (being responsible and accountable for that) and risk communication vis-à-vis the public (citizens, media, social media) and stakeholders. In turn, impact assessment requires rigorous analysis and the right sequence of the right questions[11] but not the 'use of science' to establish the risks. Risk assessment is a separate exercise, to be performed by scientists, and it has to take place prior to an IA. But one should not be naïve about it: a sound risk assessment may well be preceded by decades of independent research published in learned journals and special reports.[12] More often than not, there is lingering uncertainty about risks even after much research effort. Also, if risks are to be reduced by the application of tolerance requirements (e.g. maximum daily intake), some arbitrary prudence is imposed by, say, lowering the found 'level' or concentration at which adverse health effects may begin to appear, by a factor of 20 or even 100. This prudence may appear wise but is not 'scientific'. Judge Stephen Breyer, an advocate of the orthodoxy, is nonetheless rather critical of the problems of risk assessment in instances such as long lead times and relatively weak relationships combined with a small dose, or, the convenience of scientists in using linear mathematical models.[13] Therefore, moving from risk assessment to risk management (that

10 This logic and its implications is set out in Jacques Pelkmans, "The economics of single market regulation", in Amy Verdun and Alfred Tovias (eds.), *Mapping European Economic Integration* (Palgrave-Macmillan 2013), pp. 79 *et sqq*.

11 Quite well captured in the Commission Guidelines on Impact Assessment and relevant annexes. See http://ec.europa.eu/smart-regulation/impact/commission_guidelines/doc/iag_2009_en.pdf, to be revised in 2014.

12 There may be many different circumstances or locations to be investigated (e.g. whether cadmium in phosphate fertilizers is risky depends critically on the type and layers of soil, and this implies great variation), many usages with different dose and/or exposures or distinct conduct (e.g. of workers or consumers) and there might be very complicated human or animal or environmental aspects (e.g. indirect routings of a substance).

13 Stephen Breyer, *Breaking the vicious circle: towards effective risk regulation*, (Harvard University Press, 1993), pp. 42 *et sqq*. One stunning example of his is that two scientifically plausible models for the risk associated with aflatoxin in grain or peanuts may show risk levels differing by a factor of 40,000.

is, the IA and decision-making on risk regulation) may well need clarification and some guidance from scientists in order to ensure that the conclusions about risk and the uncertainty or restrictions or scope of the inferences are properly understood by those preparing the IA and the legislators later on.

In other words, the separation between the two should not degenerate into 'insulation'. Yet, this is more easily said than done, particularly in the complex and splintered EU system. This crucial interface is definitely an area of attention for the CSA. On the other hand, the advantages of the separation should not be forgotten: scientists should be shielded against influence from officials and politicians, as well as against pressures from business and NGOs, each with their own agendas and media or lobbying tactics. This is true for ad-hoc or permanent expert groups staffed with (part-time) scientists but just as much for the four EU Agencies mentioned before. In turn, it ought to be crystal-clear that scientists themselves cannot suffer from conflicts of interests due to research contracts with business or direct affiliations with advocacy groups or likewise NGOs.

However, the merits of separation notwithstanding, the problems with the triad system have long been shown to be more deep-seated. Upon closer scrutiny, in a number of areas such as medicines, public health (e.g. what is a carcinogen for regulatory purposes?) and environment, it has been shown that considerable discretion may exist for scientists to predict risks and to determine what is and is not a 'substantial' risk. Clearly, some of these decisions are likely to be political or at least not scientific.[14] Whereas regular risk assessment by EU Agencies is usually well done and embedded in routine structures, this is much less the case in/for other DGs. Indeed, one discerns irregularly but not infrequently, that scientific conclusions get 'translated' for policy in ways that might be regarded as 'political'. This is a difficult issue, because one has to come to operational conclusions based on risk assessments, but too much discretion can be misused by policy makers with a preset agenda. Clearly, this cannot be worked out here, but two simple illustrations might help one to appreciate this point.

2. Why science matters for policy-making: selected examples

The first example is on 'snus', a Swedish smokeless tobacco (but different from e.g. American smokeless tobacco). Snus is forbidden in the EU (except in Sweden) whereas American and some other oral tobaccos are not; needless to say, also ordinary cigarettes are not banned (although they are far more harmful, if only because of smoke, the principal culprit). Given this predicament, one would expect snus to be distinctly more harmful than other oral tobaccos, which are allowed, and than ordinary cigarettes. Under Article 11 of the tobacco directive 2001/37, the ban of snus had to be justified in a review in 2008, as no scientific evidence had ever been provided to justify the EU ban. The SCENIHR produced a report[15] summing up several health risks of snus. Since the Commission and some Member States maintain a strong policy stance on preventing 'initiation' of smoking, both the experience of snus as an aid to cessation and as a stepping-stone for initiation of smoking cigarettes is reviewed as well. The point made here is not on the purely scientific evidence – the authors are not competent of course – but on the 'use of science' to maintain the ban. In focusing on health risks of snus only, the SCENIHR report completely by-passes the underlying reason for the policy choice: why ban snus if other smokeless tobacco (more harmful than snus) and cigarettes (far more harmful than snus, e.g. more types of cancer, etc.[16]) are not banned? The ev-

14 Due to space constraints it is impossible here to do justice to the vast body of literature in this area. On science and values in risk assessment, see e.g. Deborah G. Mayo and Rachelle Hollander (eds.), "Introduction", in *Acceptable evidence: science and values in risk management*, (New York: Oxford University Press, 1991); Sheila Jasanoff, *Risk management and political culture*, (New York: Russell Sage Foundation, 1986); Sheila Jasanoff and Brian Wynne, "Science and decision-making" in Steve Rayner and Elizabeth L. Malone (eds.), *Human choices and climate change, vol. 1 : the societal framework* (Columbus, Ohio: Batelle Press, 1998), pp. 1 *et sqq.*; on the precautionary principle see i.a. Giandomenico Majone, "What price safety? The precautionary principle and its policy implications", 40 *Journal of Common Market Studies* (2002), pp. 89 *et sqq.*; Dick Taverne, *The march of unreason: science, democracy and the new fundamentalism*, (Oxford: Oxford University Press, 2005); also Stephen Breyer, *supra* note 13; on establishing a risk assessment policy, see Erik Millstone, "Science, risk and governance: radical rhetorics and the reality of reform in food safety governance", 38 *Research Policy* (2009), pp. 624 *et sqq;* on the the framing of risk assessment, see e.g. Andy C. Stirling and Ian Scoones, "From risk assessment to knowledge mapping: science, precaution and participation in disease ecology", 14 *Ecology and Society* (2009), pp. 1 *et sqq*.

15 DG SANCO, 'Health effects of smokeless tobacco products', 6 February 2008.

16 For example, snus is not a significant risk factor for cancers such as on kidneys, the bladder, lung, skin and hematopoietic cancers, all candidates in the case of cigarettes.

idence that snus may inflict harm is not discriminating evidence, other tobacco inflicts, if anything, more or far more harm. And surprisingly, the evidence on cessation and on initiation is said to be inconclusive,[17] so this would seem to be no reason to ban the product either. Indeed, Sweden has by far the least bad record on cancer in the EU-28. Yet, shortly after the SCENIHR report, the decision was taken to maintain the ban.

A second example concerns outdoor noise. The EU has an environmental noise strategy for more than a decade as such noise can inflict adverse health effects. There are two types of outdoor noise, one causing adverse health effects (mainly traffic noise from rail, air and cars/trucks) and one which merely induces annoyance. The Outdoor Noise directive 2000/14 imposes compulsory noise limits on 22 types of outdoor noise equipment (and has other regulatory provisions which do not matter for this example). The question is whether the negative externalities (market failure) from outdoor noise equipment justify such noise limits. Ultimately, this depends on the risks of adverse health effects inflicted by the use of such equipment. This is a matter of scientific risk assessment. In a recent survey of scientific work on such risks, Hellmuth et al. provide empirical evidence for issues (such as adverse health effects, diseases) under the environmental noise (framework) directive.[18] However, other than for various forms of traffic noise, no scientific evidence is available for outdoor noise emitted by equipment. Scant evidence is available from other sources: one study – perhaps not even 'scientific'- has surveyed comparative rankings of noise for Dutch citizens [19] and found that (probably) the worst instance of outdoor noise under the Outdoor Noise directive, namely construction, was ranked very low, lower than a range of traffic vehicles (and airplanes) and also lower than the neighbour's TV. All this strongly suggests that outdoor noise from equipment at worst generates annoyance. However, outdoor noise (other than in harbours and some industrial sites, which are not or scarcely populated) is very different from most traffic noise that inflicts adverse health effects: whereas the latter is permanent or has a long duration for inflicting harm, the former is temporary, if not very short-lived, and very irregular, with no noise most of the time; even building sites produce noise levels with great variation over their lifetime, and almost always during working hours only.

The conclusion is that risk assessment or other robust empirical evidence cannot be used to argue that the outdoor noise directive is justified by a market failure risking diseases due to exposure. However, this is widely taken for granted. The real reason, probably justified and strongly suggested by the history of the directive, is the great risk of fragmenting the internal market of outdoor noise equipment (would the directive be repealed) due to the return of local and national regulation, all with different and specific requirements, even though such local rules would have a dubious rationale (namely, complaints about annoyance). Such splintering is bound to be extremely costly for the equipment industry, losing economies of scale and scope (variety) and seeing its global competitiveness damaged, and ultimately for the consumers, too.

These two examples also show how the use of science is pervasive in EU policy-making, often in technical areas that are unlikely to attract much public attention and scrutiny. In turn this makes the need for a systematized way of transferring scientific knowledge into policy-making even more apparent. In this context, the role of the CSA as an interface between science and concrete regulatory and policy decisions is of particular relevance. Before commenting in more detail on the current function of the EU's CSA and how it could be improved, it is worth taking a look at the broader context in which the use of scientific knowledge takes place at the EU level.

III. SWOT analysis of the use of science in EU policy-making

Figure 1 provides a SWOT analysis of the use of science in EU policy-making. The content of the figure is briefly explained below. The authors do not pretend that this analysis is anything more than an aid

17 However these conclusions are drawn by putting on par American smokeless tobacco and snus, which is unlikely to be justified. It is also noted that, in Sweden, data does not support the hypothesis that snus is a gateway to initiation of smoking.

18 T. Hellmuth, T, Classen, R. Kim & S. Kephalopoulos, "Methodological guidance for estimating the burden of disease from environmental noise", (2012) Copenhagen/Geneva/Brussels, WHO (supported by the JRC), www.euro.who.int

19 Nomeval study, "Noise of machinery – evaluation of directive 2000/14, 12 December"' (2007) for DG Enterprise, European Commission.

Strengths	Weaknesses
(Scientific) risk assessment holds an important place in several EU areas.	Absence of clear criteria to establish what scientific evidence is needed and when it is sufficient to assess risks and/or to explain authoritatively the underlying scientific rationale(s) of a policy or technical specifications.
Experience in some DGs (JRC, SANCO) in dealing with scientific evidence.	Lack of clarity about the critical trigger(s) to shift from risk assessment – with all the caveats and often considerable uncertainty - to the application of the precautionary principle.
Experience in scientific risk assessment in four EU Agencies, supporting legislative preparation.	Unclear approach to risk, also operationally, e.g. risk-risk analysis in the current COM IA guidelines.
Impact assessment process in place and embedded in decision-making across the Commission.	Perceived lack of transparency in the wider policy community which increases a tendency to mix science and politics.
Impact Assessment Board for quality control.	Partial/selective/biased use of scientific evidence in some cases without corrections governed by guidelines.
Chief Scientific Adviser and STAC.	
Greater attention to ex post evaluation and closing the evidence-loop in the policy cycle.	
Opportunities	**Threats**
Revision of the COM Impact Assessment Guidelines.	The quality of future EU risk regulation may be impaired, absent a clear set of well-explained guidelines on the use of scientific evidence in EU decision-making.
Revision of public consultation guidelines: using better the linkages with the scientific community.	Comitology represents a threat to the proper use of science, if not at least, disciplined by compulsory transparency and good explanations in every case that a risk assessment is strongly opposed or rejected.
New Commission and European Parliament to maintain and bolster the CSA function(s).	Wider public still disconnected from EU policy debates in general and on scientific evidence in particular.
Existing services including the in-house science capacity of the Commission (JRC) can be reorganized and better exploited to channel scientific evidence into policy-making.	Use of science for specific areas of policy- making (e.g. chemical, food) may differ between Member States.
Institutionalizing and mainstreaming the role of the CSA and clarifying its link with the overall scientific evidence-gathering process.	Still insufficient capacity (in terms of the right set of skills) in EU and national administrations to ensure that scientific evidence is accurately translated in policy terms.
Member States' governments – hence, the Council – to have systematic attention for the proper 'use of science' and mimic good practices of the COM now or in future.	
Extending CSA tasks in fostering active and responsible risk communication by the Commission, with the help of scientists.	

Figure 1: SWOT Analysis of the Use of Science in EU Policy-making

to the current debate, and possibly to stimulate a far more systematic approach addressing these questions and perhaps other ones as well, based on extensive fact-finding and evidence.

In terms of *strengths,* scientific risk assessment already holds an important place in several EU policy areas and various Directorate-Generals (e.g. the Joint Research Centre and DG SANCO) have accumulated

experience in producing and using scientific evidence on a regular basis. The same can be said of scientific risk assessment in the four EU agencies, which produce scientific evidence in support of legislative preparation. This expertise can be transferred elsewhere or further channelled into decision-making. Despite the sometimes acrimonious debates on a few contentious issues, a lot of EU risk assessment works well and is professionally conducted and even developed. For example, outside the GMO area, EFSA scientific opinions are routinely accepted as state-of-the-art. In the first ten years, over 2200 scientific opinions have been published in the EFSA Journal, including nine innovative risk assessment methodologies.[20] Similarly, EMA and ECHA enjoy a good reputation. These positive attributes are far too little noticed. In addition, EU impact assessment (IA) was introduced over a decade ago.[21] Given the fact that impact assessment is now fully embedded in the preparation of legislative (and other) proposals of the European Commission, one could leverage IA for furthering the debate on risk assessment. The CSA seems well placed to take the lead to stimulate a well-thought-out risk assessment policy (RAP) for expert committees and Agencies. The CSA is not a risk manager but a scientist tasked with improving scientific evidence to be used by the EU. The creation of the Impact Assessment Board (IAB) in 2007 has inserted an element of regular oversight in the current system. While the IAB focuses essentially on compliance with the Commission Impact Assessment Guidelines and less so on the content and merit of the (scientific) evidence underpinning each impact assessment, this "quality control function" is *per se* an asset of the current system. It could also be exploited to promote a better 'use of science' in policy appraisal, for instance by pointing out that a risk assessment might have been necessary/appropriate on a certain occasion or by probing those who drafted the impact assessment on what type of evidence was used and why, and whether the evidence was scientific, rigorous and/ or the best available. In this respect, the newly created CSA function is an additional strength as it could be called upon to provide feedback when scientific evidence is used in impact assessment. The Science & Technology Advisory Council (STAC)[22] and the reinforced links with the broader scientific community reported by the current CSA are additional assets from this perspective. Finally, the growing emphasis on ex post evaluation and on the need to close the "evidence loop" underpinning the policy decisions,[23] provide an additional entry point for scientific evidence in EU policy-making.

Some of the current *weaknesses* will come as no surprise and have already been discussed by others or in relation to specific instances of evidence use (e.g. impact assessment).[24] A central problem in the current use of scientific evidence at EU level is the absence of clear criteria to establish what type of scientific evidence is needed and when it is sufficient to assess risks and/or to explain authoritatively the underlying scientific rationale(s) of a policy or technical specifications. In this respect, EU policy-makers have not always displayed a clear and predictable approach to this point, particularly when it comes to the assessment of risk. Perhaps the greatest immediate problem is the political discretion of judging such risk assessments during comitology or even the Council in rare cases.

This issue is also visible operationally: thus, the current Commission Impact Assessment Guidelines do not offer any guidance on how to perform risk assessment – prior to the IA - or on how to examine the trade-offs between different risks as well as the opportunity cost and rewards that can derive from avoiding/reducing a certain risk.[25] While the impact assessment itself is not the right place to provide a full scientific analysis on a given issue, it is certainly one of the best tools to translate the results of science in policy terms and to increase information and transparency on the cost and benefit (also in qualita-

20 See EFSA Journal, Special issue (2012), on "Scientific achievements, challenges and perspectives of the EFSA", available on the Internet at www.efsa.europa.eu (last accessed September 2014).

21 A broader discussion on the strengths and weaknesses of current EU impact assessment practice falls outside the scope of this article. For recent reflection on this particular point, see e.g. Alberto Alemanno and Anne. C. Meuwese, "Impact Assessment of EU Non-Legislative Rulemaking: The Missing Link in "New" Comitology", 19 *European Law Journal*, pp. 76 *et sqq*. (2013); Andrea Renda, *Law and Economics in the RIA World,* (Cambridge: Intersentia, 2011).

22 Further details on the STAC are available on the Internet at: http://ec.europa.eu/commission_2010-2014/president/advisory-council/index_en.htm.

23 See Communication on smart regulation, *supra* note 7.

24 See for instance Ragnar E. Lofstedt, "Risk versus Hazard – How to Regulate in the 21st Century", 2 *European Journal of Risk Regulation* (2011), pp. 149 *et sqq*. On the case of impact assessment, see *supra* note 21.

25 This has been noted elsewhere, see for instance the Minutes of the first STAC meeting available on the Internet at: http://ec.europa.eu/commission_2010-2014/president/pdf/advisory-council/4_-_minutes_meeting_feb_2013.pdf (last accessed September 2014). See also Ragnar Lofstedt, *supra* note 24.

tive terms) implications of increasing/reducing a certain risk. A lack of clarity when using scientific evidence in policy debates contributes to the perceived lack of transparency in the wider policy community. Ultimately this undermines trust in the decision-making process and facilitates an unproductive (and sometimes damaging) mixture of science with politics.[26] The problem is likely to become more frequent when decision-makers or officials have relatively little hesitation to invoke the precautionary principle, based on what scientists would tend to denote simply as insufficient risk assessment, as a basis for drastic stops or bans or restrictive rules.

In terms of *opportunities*, the ongoing revision of the Commission impact assessment guidelines offers an occasion to address some of the weaknesses (e.g. the assessment of risks) identified above. The forthcoming review of Commission public consultation guidelines also provides a new chance to improve linkages with the scientific community and foster the development of a fruitful debate between science and society, beyond the traditional community of stakeholders that regularly contribute to policy making.[27] The arrival of a new European Parliament and a new Commission provides a window of opportunity to mainstream the role of the CSA and clarify its link with the overall scientific evidence-gathering process. It could also be an occasion to reorganize more effectively the in-house scientific capacity of the European Commission (i.e., the JRC but also EU agencies) to ensure that their expertise is exploited better and fed into policy debates. An opportunity might also be seen in the extension of the CSA mandate to foster active and responsible 'risk communication' by the Commission, but explicitly and systematically with the help of scientists. Finally, if the links that the current CSA has established with the scientific community in the various EU Member States are further developed, this could lead Member States' governments – hence, the Council – to pay systematic attention to the proper 'use of science' and mimic good practices of the Commission.[28]

As regards *threats*, the quality of future policy decisions risks being impaired if a clear set of well-explained guidelines on the use of scientific evidence in EU decision-making is not established, first of all for the European Commission but in fact for all EU bodies. This is not so much a question of developing new guiding principles – which are already informally available at e.g. the Organisation for Economic Co-operation and Development (OECD) and the World Health Organisation (WHO) - but is rather about ensuring that those who are not routinely involved in risk assessment and are not scientist by training, are guided and bound by rules and transparency about how to read risk assessment, understand its properties and the proper way it ought to be utilised for policy thinking. Given the increasing complexity of current policy decisions, an *ad hoc* approach to the use of scientific evidence can only exacerbate the perceived lack of transparency among many stakeholders and reinforce the adversarial nature of policy debates. Indeed, sometimes in EU decision-making bodies, but also by some Member States in some issues, as well as by NGOs and business, one observes tactical, strategic and marketing manoeuvres to selectively read and emphasise evidence so as to promote one's own agenda, rather than to serve the EU public interest by respecting the rigour and properties of risk assessment. In this respect, comitology represents a threat to the proper use of science, if not, at least, disciplined by compulsory transparency and good explanations in every case that a risk assessment is strongly opposed or rejected.

Along the same lines, there is a risk that the wider public remains disconnected from EU decision-making, particularly if the implications of future developments in science and technology are not communicated extensively and debated properly. Valuable suggestions on this point were put forward by the STAC as regards engaging citizens in situation of change.[29]

26 On this point, see *supra*, note 24.

27 On this point see STAC, "Science for an informed, sustainable and inclusive knowledge society", and Ortwin Renn, "To be responsive to public needs, we should be sensitive to gut feelings, but should subordinate our policies to them" in BEPA, "Science and Society. Time for a new deal", 3 Berlaymont Paper (2013), pp. 11 *et sqq*, available on the Internet at: http://ec.europa.eu/commission_2010-2014/president/advisory-council/documents/berl_papers_issue_3.pdf (last accessed September 2014).

28 In relation to this point, see also a recent quote from CSA Anne Glover: "I believe that it can only be useful to MEPs and ministers, because they would come here with a scientific briefing taking account of issues within all the member states. We would be ahead of the game if Europe organised itself like that" in "EU science advisor 'Lots of policies are not based on evidence'", Euractiv, 24 July 2012, available on the Internet at: http://www.euractiv.com/innovation-enterprise/chief-scientifc-adviser-policy-p-interview-514074 (last accessed September 2014).

29 See STAC, *supra* note 27. On public engagement with science see also Jack Stilgoe and James Wilsdon, "The new politics of public engagement with science?" in Richard Holliman et al. (ed.), *Investigating science communication in the information age: implications for public engagement and popular media* , (Oxford: Oxford University Press, 2008).

IV. The Chief Scientific Adviser: First achievements

The official mandate of the first Chief Scientific Advisor includes six tasks, one being very general, one on risk communication, one on the provision of analysis and opinions on 'major' proposals of EU risk regulation (or other policies) – in particular, on scientific evidence - to the Commission president, and three on building networks e.g. with advisory groups/committees and EU Agencies and with similar functions at Member State level.

What early achievements of the CSA can be recorded? When the first CSA took office in January 2012, only three countries, the United Kingdom (Professor Glover herself was CSA for Scotland),[30] Ireland and the Czech Republic had a similar role already in place. Today, about half of the EU Member States have a similar figure and an informal network between existing CSAs or their equivalents has recently been set up.[31] This could be read as a sign that the need to better channel or even strengthen the role of scientific evidence in decision-making both at national and EU level is acknowledged and, more importantly, acted upon, a first tangible consequence of the CSA function. In addition, available public sources and the feedback collected directly from Professor Glover allow us to point to a series of additional achievements to date:

- The appointment of a Science & Technology Advisory Council (STAC), an independent and informal group of experts from academia, business and civil society reporting to the President of the European Commission in January 2013. One of STAC's central missions is to foster dialogue between science and society.
- The creation of a formal foresight network across the European Commission services. It includes 21 Directorate-Generals and about 200 members of staff who are formally assigned to the network. Its purpose is to challenge the Commission services in identifying what scientific evidence they will need. It also facilitates the coordination of policies, puts in contact people who would not necessarily have interacted otherwise, and stimulates interdisciplinary thinking, which is necessary in science today. In some areas this already works (e.g. climate change) at the impact assessment level, too, in other areas this is not the case. This network is "meant to coordinate thinking before putting policies together",[32] it has some 40-50 files on new technology, 3D printing, the internet of things, synthetic biology (etc.) and those involved try to see and communicate what would be the impact on their policy area. The group makes a SWOT analysis of each area.
- Reinforced dialogue and cooperation between the in-house science service of the Joint Research Centre (JRC) of the European Commission and the broader scientific community. A Letter of Intent[33] was signed in 2011 between the European Academies Science Advisory Council (EASAC)[34] and JRC "in the name of the common goal to support policy making through independent scientific research". This includes making available to the scientific community the work programme of the Commission and where the European Commission will need scientific evidence. Reportedly, this is welcome by researchers as they feel this can increase the impact of their research on decisions, and avoid the classical case of scientific evidence arriving too late. On the other hand, the letter of intent clarifies that the two institutions will remain independent from each other.[35] A first example of JRC-EASAC cooperation led to a report on the impact of engineered nanomaterials on human health.[36]

The first achievements are clearly organisational in nature. Therefore, a direct impact in terms of im-

30 Note that in the UK the post exists since 1964. On that specific experience and more broadly on the use of scientific advice, see Robert Doubleday and James Wilsdon, "Future directions for scientific advice in Whitehall", Project Report (London: Alliance for Useful Evidence & Cambridge Centre for Science and Policy, 2013), available on the Internet at: http://sro.sussex.ac.uk/47848/

31 "Evidence-based Union? A new alliance for science advice in Europe", The Guardian, 24 June 2014, available on the Internet at: http://www.theguardian.com/science/political-science/2014/jun/23/evidence-based-union-a-new-alliance-for-science-advice-in-europe (last accessed September 2014).

32 Interview with Anne Glover, 8 July 2014.

33 The text of the Letter of Intent is available on the Internet at: http://www.easac.eu/fileadmin/PDF_s/Letter_of_intent_final.pdf

34 Further detail on EASAC's composition and activities available at: http://www.easac.eu/home.html. Key sectors on which EASAC provides advice to the European Commission are: climate change, agriculture and food security, and public health.

35 As explained in point 4 of the Letter of Intent (see *supra*, note 33), the two organisations both work in the field of science advice for the EU, but their roles are quite distinct.

36 EASAC-JRC, "Impact of engineered nanomaterials on health: considerations for benefit-risk assessment", Joint EASAC-JRC Report (2011), available on the Internet at: http://ihcp.jrc.ec.europa.eu/our_activities/nanotechnology/nanoreport-10-11/JRC-EASAC-report.pdf (last accessed September 2014).

proved use of science for EU risk regulation is not yet clear. In some cases the CSA function is also contested,[37] particularly as regards the personal advice to the Commission President, which has so far remained confidential to 'keep science away from politics'.

V. Conclusions and Recommendations

Building on the current strengths and opportunities described above and the contribution of the CSA in the last two and a half years, the authors propose the following suggestions to improve the use of scientific evidence in EU-policy- making. Specifically:

- A set of clear guidelines on how to deal with risk should be developed. This is not so much about introducing new concepts (although some non-scientific guidance for risk assessment may be included, with the help of scientists) but rather about ensuring that players in EU decision-making that are not routinely involved in risk assessment and not scientists in the first place, are guided and bound by rules and transparency requirements on how to read risk assessment and better understand its properties and how it ought to be utilised for policy thinking.
- The growing importance of comitology following the adoption of the Lisbon Treaty cannot be overlooked. Transparency in that context is essential as regards the use or rejection of evidence in general and of science in particular.[38]
- To strengthen and streamline the use of science in EU policy-making, the CSA should become a member of the Impact Assessment Board[39] to provide advice and quality control in all cases where scientific evidence is relevant to make a decision.
- The CSA should also be tasked with developing, together with the STAC, a checklist for reflection on the so-called 'deficits' in risk assessment.[40] These deficits concern the gathering and interpreting of knowledge (failure to detect 'early warnings', lack of adequate factual knowledge, omission of knowledge about stakeholder perceptions/concerns), disputed or biased knowledge, failure to properly evaluate a risk as (un)acceptable to society, the misrepresentation of risk due to biases or selectivity, and three deficits related to complexity of systems (how components interact, system changes causing new risks, over- or under-reliance of formal models).
- Where risk assessment requires non-scientific guidance on what questions should be asked (scope), what prudence should be applied for e.g. tolerance levels, and e.g. whether linear models may be regarded as appropriate, (etc.), some kind of 'risk assessment policy' ought to be formulated by policymakers in close consultation with scientists.[41]
- In the longer term, one could imagine a Risk Assessment Board for quality control purposes and to ensure that the evidence-base underpinning decisions is updated and follows the progress of science. The role of such a Board should be less pervasive than the IAB one (as scientists should not be 'controlled' a priori) and would be activated only when risk assessments are contested on serious grounds. A Risk Assessment Board can only function properly once clear guidance on how to perform and use risk assessment is developed and regularly applied. The work of the Board could be supported by the JRC.
- EU Member States should have systematic attention for the proper 'use of science'. A crucial starting point would be to be explicit whenever a decision is based on national preferences rather than on insufficiently developed scientific evidence. This would counter the tendency to mix science with politics, ultimately undermining trust in policy-debates.

37 See the recent reaction of Corporate Europe Observatory, at: http://corporateeurope.org/power-lobbies/2014/07/position-chief-scientific-advisor-president-european-commission

38 In relation to this point see Alemanno and Meuwese, *supra* note 21.

39 On this point, see also the recent letter of BusinessEurope to President Barroso of 6 June 2014, available on the Internet at: http://www.businesseurope.eu/content/default.asp?PageID=568&DocID=33005 (last accessed September 2014).

40 The Geneva International Risk Governance Council offers an interesting example. See IRGC, Risk governance deficits, Geneva, www.irgc.org (2009).

41 See Erik Millstone, "Science, risk and governance: radical rhetorics and the reality of reform in food safety governance", 38 *Research Policy* (2009), pp. 624 *et sqq*.