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Recent developments and new frontiers

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*Recent Trends in Impact Assessment in Europe
and their implications for using impact assessment
in the development of European Union policies*

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Introduction

This paper was drafted by Lorenzo Allio, a Director at [allio|rodrigoconsulting](#), as a complementing document to his presentation held at the SIGMA Workshop "Recent Trends in Impact Assessment in Europe and their implications for using impact assessment in the development of European Union Policies" of 14 June in Zagreb.

The paper highlights the main characteristics of the Impact Assessment (IA) system of the European Commission (EC); reports on recent developments; and offers a few considerations as to the possible challenges that the system is likely to face in the near future.

Background

The policy of IA: A snapshot

Provisions for IA are included only indirectly in the European Union's (EU) Treaties, notably in a Protocol attached to the Amsterdam Treaty in 1996.¹ Legal bases for sectoral impact assessments can be found in the EU Treaty.² The most important document binding the EU institutions to carrying out IA is the 2003 Inter-Institutional Agreement on Better Law-making,³ which is accompanied by a Common Approach to Impact Assessment.⁴

A partial and sectoral approach to policy formulation and, consequently, to IA characterised the Commission till the end of the 1990s. Each DG majorly involved in policy initiatives had developed its own tools and responsibility for timing and methods was fully de-centralised. Different instruments were used to assess business, environmental, gender, health, financial impacts and so on.

The approach radically changed with the launch in 2002 of an "Action Plan on Better Law-making", which progressively catapulted the Commission's Secretariat-General (SecGen) as the sole champion for the reform agenda. In particular, the Directorate-General (DG) Environment and DG Budget first – and DG Enterprise later on – were brought under the umbrella of an "integrated" vision for IA,⁵ which reflected centralised procedures and organisational arrangements. Hence the SecGen coordinated the process of drafting the IA Guidelines, of which it is the depository.

The Commission formally and officially speaks of "impact assessment" (instead of "regulatory" impact assessment) because the scope of application of the system covers both the legislative proposals and non-legislative proposals (in particular White Papers, action plans, expenditure programmes) included in the annual Legislative and Work Programme. Since 2009, the Commission considers assessing also "major" implementing decisions (undergoing the so-called "comitology" procedure), which fall outside the Commission Legislative and Work Programme (CLWP).

¹ See *Protocol on the Application of the Principles of Subsidiarity and Proportionality*, in OJ C 340 of 10 November 1997.

² On environmental protection, Article 6 of the consolidated Treaty on the functioning of the European Union requires that account of the sustainable development dimension is taken when defining and implementing Community policies. Article 191(3) provides that the Community must take account of the potential benefits and costs of action (or lack of action) when preparing its policies on the environment. Article 147 requires the Community to take account of the objective of a high level of employment. Articles 168 and 169 require the Community to achieve high levels of human health protection and consumer protection. Article 173 focuses on measures to improve the business environment. Finally, the Commission decided in March 2001 that any "proposal for legislation and any draft instrument to be adopted by the Commission will (...) first be scrutinised for compatibility with [the EU Charter of fundamental rights]." (EC, 2001a:3).

³ OJ, C 321 of 31 December 2003, p.1.

⁴ http://ec.europa.eu/governance/impact/docs/ii_common_approach_to_ia.pdf.

⁵ Allio, L. (2009), *The emergence of Better Regulation in the EU*, PhD Thesis, King's College London (unpublished). The attribute "integrated" denotes that all Commission services shall follow the same approach, consisting on a single template considering the economic, social and environmental impacts of the proposal.

Above all, the IA process was linked to both the forward planning cycle (i.e. the yearly agenda setting of the Commission) and the budgetary cycle. And in 2007, an internal oversight body – the Impact Assessment Board (IAB) – was created within the SecGen to check the quality of draft IAs. The SecGen also coordinates the machinery of inter-service consultation and manages the Commission policy on transparency and access to documents.

Over the years, the Commission reform agenda has changed in rationale, shifting for instance from a “governance-driven” towards a “competitiveness-oriented” approach in 2005 – most notably by recalibrating Better Regulation onto “Growth and Jobs”.⁶ The consequences for IA were that – to paraphrase George Orwell – while keeping the integrated approach, the economic and competitiveness impacts of a proposal were somehow considered as “more equal” than the other two categories to be assessed, namely the social and environmental impacts.⁷ Organisationally, most political weight on Better Regulation and IA was allocated in the hand of the Vice-President of the Commission in charge of Industrial Affairs.

In 2009, the President of the Commission took direct political leadership and responsibility for the reform programme.⁸ The new “Smart Regulation”⁹ course not only reaffirmed the commitment to maintain pressure on reducing administrative burdens from EU legislation. It also expressly sought to “join up” the policy cycle’s extremes: more attention had been put to developing post-implementation reviews, also in relation to a further enhanced *ex ante* assessment system. The resulting 2010 Communication on Smart Regulation has hence introduced new simplification and evaluation tools such as the so-called “fitness checks”.¹⁰

The institutional and procedural arrangements

The Commission IA system relies on a coordinating centre (the IA Unit in the SecGen) and a network of IA (or Evaluation) Units in almost all the DGs for direct (sectoral) support.

While there is no formal external screening of the Commission IAs,¹¹ the oversight function within the institution is multiple and rather effective. The most evident element of the quality check system is the IAB, which serves as an independent internal quality control body.¹² The IAB was established in 2007 to review the quality of individual RIAs and the overall soundness of the RIAs produced by the Commission services. It issues opinions that may contain negative comments and requests for additional analysis. The IAB members are high-level officials from the Commission departments most directly linked with the three pillars of the impact assessment – economic, social and environmental impacts.

Two important horizontal mechanisms ensure that adequate expertise is inputted to the IA analysis from the various parts of the Commission, ensuring at the same time further quality oversight. The first mechanism consists of the “IA Steering Groups”, which are established every time a IA is carried out. The work of the Steering Group is intended to pave the way for the subsequent “Inter-Service Consultation”. This round of internal consultation across DGs follows the opinion of the IAB, and constitutes the second mechanism for internal coordination on IA.

In 2003, the SecGen issued the first “IA Guidelines” to assist Commission officials in preparing IAs. The document, which is not legally binding but mandatory on all DGs, has been revised and significantly

⁶ European Commission, *Better Regulation for Growth and Jobs in the European Union*, COM(2005) 97 final of 16 March 2005.

⁷ Allio, L. (2010), “Keeping the centre of gravity work: Impact assessment, scientific advice and regulatory reform”, in *European Journal of Risk Regulation*, 1(1): 76-80, at p.77.

⁸ <http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/09/400&format=HTML&aged=0&language=EN&guiLanguage=en>; and President Barroso’s *Political Guidelines for the Next Commission*, 2009.

⁹ European Commission, *Smart Regulation in the European Union*, COM(2010) 543 final of 10 October 2010. See also the general Commission webpage http://ec.europa.eu/governance/better_regulation/index_en.htm.

¹⁰ European Commission, *EU regulatory fitness*, COM(2012) 746 final of 12 December 2012.

¹¹ The European Parliament has nonetheless recently established its own IA unit to – among other – review the reports received from the Commission.

¹² See http://ec.europa.eu/governance/impact/iab/iab_en.htm.

upgraded in 2005 and 2009. The latest revision¹³ was produced after public consultation. The guidelines explain in details the nature and various steps of a IA and provide advice on how and when to prepare it. A template for the assessment is also included. A number of annexes to the guidelines provide detailed descriptions on methodologies as well as concrete examples. Particularly useful is the online library of best practices, which is structured around the key steps of the IA process. The library is attached as Annex 14 to the guidelines but can also be accessed directly online.¹⁴

The Commission applies a two-stage approach to IA, on the basis of the so-called "principle of proportionate analysis". This translates in practice with the obligation to produce preliminary "roadmaps" on all proposals, while more comprehensive "Impact Assessments" are carried out only on selected items of the CWLP. It is the SecGen, the IAB and individual DGs that decide, on an annual basis, which proposals undergo an IA. The services are then invited to match the depth of the analysis necessary with the time and financial resources at disposal. This flexibility is due to the fact that RIAs are produced at different steps of the policy formulation process, on dossier with different legal status and political salience.

The internal procedural steps that the IA drafters must follow are described in the Commission IA Guidelines:¹⁵

- Once the DG planning is defined, the responsible unit starts working on the "roadmap", often with support from the DG's IA Unit. A roadmap should include information on each of the analytical steps and the timing of the IA and outline the consultation plan – or explain why an IA is not necessary.
- Roadmaps are circulated internally for information and comments before the adoption of the CLWP, and to assess the opportunity or need to proceed to a fully-fledged IA.
- An IA Steering Group is set up for each RIA and contributes to all phases of the IA work. The Group is coordinate by the SecGen. It reviews the final draft of the IA report before it is submitted to the IAB. A member of the DG's IA Unit normally sits in the Group, together with representatives from DGs whose policies are likely to be affected.
- Parallel to the work on the IA, the official responsible for the dossier consults the interested parties, collect expertise and analyse the results. The findings are to be presented in draft form to the IAB for its opinion at least 8 weeks before the Inter-Service Consultation (ISC) starts.
- The IAB may request re-submission of a draft IA, as it deems appropriate. Final adjustments to the RIA report may need to be taken on board reflecting also comments received during the ISC.
- The lead unit prepares an explanatory memorandum accompanying the draft proposal, in which it sets out the options that have been considered, their potential economic, social and environmental impacts, and how the recommendations of the IAB have been incorporated.
- Further to the ISC, the IA report and executive summary are presented to the College and published as two separate Staff Working Documents once the proposal is adopted.

Training on IA is systematically provided through Commission internal seminars designed and run by the SecGen in collaboration with the IAB. Training was clearly intensified over the years. External institutes and consultants sometimes provide additional training. Anecdotal evidence estimates the number of the officials trained on IA so far in hundreds.

¹³ See http://ec.europa.eu/governance/impact/commission_guidelines/commission_guidelines_en.htm.

¹⁴ http://ec.europa.eu/governance/impact/commission_guidelines/best_pract_lib_en.htm.

¹⁵ European Commission IA Guidelines, 2009, p.7ff.

IA, Consultation and publication

The Commission consultation process normally unfolds over three phases: investigatory “Green Papers” are followed by more strategic and concrete “White Papers”, which on their turn constitute the basis of the actual proposals (in forms of “Communications”). The standards for consultation introduced in 2002 (including the recently expanded 12 weeks as minimum consultation period) do not apply however to the consultation practices undertaken by the services in the IA process. The latter is not formalised, and for instance IA drafts are not posted for notice-and-comment. This notwithstanding, the IA Guidelines explicitly mention the need to consult while preparing an IA and as a part of its mandate, the IAB also checks that consultation standards are adequately applied.

Publication is a key component of the Commission IA system both in recognition of the necessity to guarantee access to as much information as possible but also in relation to the potential control function that public screening has on the quality of IA reports. While the IAB opinions are not binding, they are seriously considered and most of the time the remarks by the IAB are taken on board by the services also thanks to the fact the IAB recommendations eventually become public and failure to take duly account of them may weaken the DG’s position. Moreover, this provides additional incentives for ever more rigorous assessments. Published are:

- the roadmaps;
- the IAB opinion on the draft IAs; and
- the final IA reports, once the final proposal is adopted by the Commission.

All these documents are available on the same portal of the Commission, which hence serves as one-stop-shop for IA at the EU level.¹⁶

Some challenges for the EC IA system

Against this background, a number of challenges can be identified that are not necessarily exclusive of the EU level but which acquire a specifically important relevance there, compared with other jurisdictions at national or non-European level. The challenges may be summarised in the paragraphs below.

From producing to using IA

Over the past decade, there has been a positive (and to a certain extent steep) learning curve within the Commission on how to produce IAs. The IAB annual reports indicate upwards trends in the quality of the draft IAs screened, although the Board itself has tightened the sharpness of its quality standards. Since 2002 until 2011 the Commission produced 750 IAs (97 IAs in 2012); resubmissions to the IAB increased from 9% in 2007 to 47% in 2012.¹⁷ A comparison between the performance of the UK IA system and the EC system also provided comforting findings.¹⁸

The next challenge, however, is upgrading the capacity to use IA, both internally and in relation to the other institutions and the Member States. Using IA can help decision-makers in a number of ways, including by producing new knowledge of the policy problem; by better grasping the implications of their decisions; or again by contributing to enhance relations between relevant actors. This can lead them to modify the design of a policy proposal or to exploit IA to justify a given political position.

¹⁶ http://ec.europa.eu/governance/impact/planned_ia/planned_ia_en.htm and http://ec.europa.eu/governance/impact/ia_carried_out/cia_2013_en.htm, for the roadmaps since 2008 and the RIAs since 2003, respectively.

¹⁷ See the IAB Annual report for 2012, http://ec.europa.eu/governance/impact/key_docs/docs/iab_report_2012_en_final.pdf.

¹⁸ Fritsch, O. et al. (2012), *Regulatory quality in the European Commission and the UK: Old questions and new findings*, CEPS Working Document nr.362, Brussels.

A further step relates to the lessons that the EU institutions have learned and can still learn from producing and using IAs, and from applying Smart Regulation practices more in general. For example, we still do not have enough evidence to answer the question whether IA has led the EU institutions to a more systematic usage of responsive and “smart regulation” flexibly deploying policy mixes and instruments.¹⁹

Bridging levels of government

There is general agreement that Smart Regulation is a shared responsibility between the EU institutions and the Member States. In practice, however, this principle faces difficulties – and the IA area well epitomises them.

The notion of “integrated” IA is shifting from the idea of (equally) considering economic, social and environmental impact to the more encompassing notion of an IA also including subsidiarity tests. “European Added Value” studies are increasingly requested pieces of evidence supporting EU proposals.²⁰ Since the Treaty of Lisbon places national parliaments as the watchdogs for these types of tests and gives them whistle-blower power, the national level is called upon to bear greater responsibility and to play a more active role in the overall IA system. Vertical organisational and methodological distinction may progressively blur, with also the regional dimension of regulatory impacts acquiring bigger relevance.

Two sets of problems arise in this context. On the one hand, Member States – by which we understand here both governments and national assemblies – are clearly variously (but on average: worse) equipped than the Commission in terms of IA capacity. National IA systems have not been institutionalised to the same extent and there is an evident adoption (legal requirement) vs. implementation (actual delivery) gap. Moreover, national authorities have not learned how to use the IA to engage in regulatory conversations and policy dialogue with the Commission. There is confusion as to whether the preparation of the IA is yet another opportunity to make domestic interests heard; to produce counter-IAs; or to respond to domestic pressure groups that feel harmed by the IA of the Commission. There is also an awareness deficit. Bringing every institutional actor across the Union up to cruising speed has so far proved to be a daunting endeavour.

On the other hand, there should be formal consistency on what is meant with Smart Regulation in general, and IA in particular. Despite the remarkable diffusion of the notion of (regulatory) IA, there has not been convergence towards the EU IA model among the Member States. It is regrettable that the leading (Nordic and Anglo-Saxon) countries in Europe have in the past decade insisted more on rather narrow and simplistic versions of IA – the administrative burden campaign, which challenges the encompassing and more balanced approach promoted by the Commission. The EU IA insists on analysing different regulatory impact components, whereas the emphasis on “red tape” pushes us back to the old logic of special assessments, neglects to consider regulatory benefits, and tends to focus on selected stakeholders, only. This clearly does not help mainstreaming the EU IA approach, and invites laggard Member States to pick low hanging fruits without engaging in more radical reforms.

Not only “closing” but also “creating” the policy loop

This point is closely associated with the one just raised. The Commission has taken the good practice of starting drafting its IAs early in the policy formulation process quite seriously. Through several mechanisms, the Commission IAs are produced early enough to stimulate learning among the different DGs and to enable the SecGen to coordinate the policy formulation process. Hence, the problem is not so much about the issue of “when does the IA start” since most EU thinking on proposals does not start from the IA – it starts rather from previous White Papers, reflection groups, conferences of stakeholders etc.

¹⁹ On this understanding of the “Smart Regulation” concept, see the 2013 *Regulation & Governance* Special Issue on Responsive Regulation, at <http://onlinelibrary.wiley.com/doi/10.1111/rego.2013.7.issue-1/issuetoc>.

²⁰ See <http://www.europarl.europa.eu/aboutparliament/en/0083c7a4db/Think-Tank.html#value>.

The main challenge seems instead to be linked to ensuring a timely “flow” of relevant and objective findings from the various analytical stages. Two are the open fronts in this respect. The first one is arguably also the one that bears the most relevant potential. Assessing regulatory outcomes through ex post evaluations is fundamental to close the policy cycle, as such evaluations constitute the natural complement to problem identification and baseline scenario setting – two critical steps in the development of each IA. The Commission is expected to issue a Communication on the matter and put draft guidelines to public consultation in the second half of this year. Yet, systematic ex post evaluation of regulatory intervention is challenging for a number of reasons:

- Data collection is costly (not least because of poor statistically harmonised databases), and it is methodologically and empirically difficult to single out the distinctive direct and indirect impacts of regulatory factors.
- Real-world situations are complex, resulting from regulatory and non-regulatory variables.
- A further complicating factor is matching the timing between the evaluation cycle and the political and regulatory agenda, so that the evaluation findings can serve as useful and timely inputs.
- Finally, there are structural institutional gaps between the implementation and the evaluation phases, which do not prevent the formation of biases.

The second open front refers less to “closing the policy cycle” than to creating an inter-institutional dialogic culture throughout the decision-making process. Updating the IA further to the negotiations that took place during the legislative process is really critical, and both the European Parliament and the Council are called upon to robustly enhancing their capacity to do so. The challenge is to create incentives for Members of the European Parliament and government representatives, respectively, to commit to such unique logic and anchoring a “dynamic IA” in the political discussions. There is no other jurisdiction where elected assemblies perform systematic IAs of their substantive amendments, or where executives revise their IAs at the end of a parliamentary debate. The EU Smart Regulation strategy is very ambitious in this respect, and it implies that the truly main function of an IA is to understand and challenge prior policy thinking, rather than generating exact regulatory impact calculations. The current inter-institutional Common Approach to IA is a basis to build upon, but a more systemic rooting of IA in the EU administrative law is required. As in the case of ex post evaluation, also on this front the EU institutions cannot benefit from wide-spread international experience to learn from and a try-and-learn component of the reform agenda seems to be inevitable.

Rationalising the scope of application

The EU IA initially applied to policy-related and legislative proposals only. This partly reflected the concern of linking IA with the Commission strategic planning mentioned in the introduction. It is nonetheless not a mystery that the Commission does not follow its own criterion of impact assessing all items included in the annual CLWP. Increasingly, also items falling under the so-called “comitology” procedures are susceptible to be impact assessed. On the other hand, there is still a grey zone with regard to decision taken by EU agencies.

This evolution bears a number of challenges, among which the following can be highlighted. First, there is a need to adapt the original approach to the tool, since the original IA analytical steps are more appropriate for early stage assessment of broad policy options than for assessing detailed and technical comitology decisions (which are often severely limited by the authorizing instrument). In addition, the current IA system would prove excessively time-consuming with the obligatory IAB intervention and inter-service consultation – something that might be disproportionate for many comitology decisions.

Second, the potential scope of application of IA expands drastically if we consider the EU regulatory (in the sense of: “US rulemaking”) activity. International experience shows that targeting and selection criteria enable governments to spend more IA resources on those proposals that really deserve the most in terms of consultation and economic analysis. The EU system is in this respect both simplistic and rather

opaque. The selection criteria are often monetary – but problematic for the Commission, given that (tentative) monetary values of impacts on 27 jurisdictions are hard to quantify at an early stage. But there are more legal-political criteria. There is an increasing need for the Commission more radically targeting IA and IA efforts (beyond the roadmap approach), by not wasting too many resources on appraisals of white papers, pilot projects, and items that are not-regulatory.

Third, the Treaty of Lisbon provisions oblige the Commission and Parliament to engage more substantially than under the previous comitology regimes. Still, none of the measures implementing Articles 290 and 291 TFEU took care of incorporating IA into their new procedures. Among other open fronts, this leaves Parliament with unresolved capacity to ensure the control over the targeted application of the evidence-based principle to regulatory decisions.

Expanding the analysis

A final challenge intrinsic to the IA tool refers to its very nature. Each IA is in fact limited by the fact that – no matter how robust its underlying analysis is – it can provide only an indication of the marginal net impact of a single piece of legislation. Cumulative and aggregate regulatory impacts are difficult to calculate from the methodologies typically used in IAs, such as benefit-cost and cost-effectiveness analysis. Also at the EU level, there is a need to better understand the overall, societal impacts of the stock of regulations already in force, and the changes brought about by new regulatory interventions, as a whole.

This challenge is linked to the methodological complexity of refining cost and benefits calculations. It implies identifying indirect and unintended consequences; assessing for instance substitution as well as risk-risk scenarios; and bridging micro-economic impacts (such as compliance costs; consumer price variations; and demand-offer flexibility) with macro-economic implications (such as shifts in R&D investments; de-location and job diversion strategies; behavioural changes etc.).

Exactly such encompassing character, which EU IAs aim at, constitutes probably one of the biggest, overarching conceptual challenges that the newly established Directorate for IA in the European Parliament will have to face – notably when it is decided to carry out substitute or complementary specific analyses beyond the original Commission IA. Intervening on the original analysis with changed framework variables (as suggested for instance by a determined amendment) may not be easily brought back to applying sensitivity analysis but might require shaping again the whole IA approach.

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Lugano, 3 June 2013