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Impact Assessment of EU Non-Legislative Rulemaking: The Missing Link in 'New Comitology'

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Abstract: *Impact assessment (IA) has gone from an innocuous technical tool typically used in the pre-legislative phase to an instrument at the heart of the European institutional machinery. However—in deviation from its roots as a tool governing delegated rulemaking in the US—most experience with IA in the EU has been gathered in a legislative context. Against the background of the recent evolution of the EU's old 'comitology' system into a two-track system of delegated acts and implementing measures, this contribution discusses in three parts the 'whys,' 'whats' and 'hows' of extending IA to 'non-legislative rulemaking.' It explores various aspects of the rulemaking process that IA—if properly applied—could strengthen: consultation, control and quality.*

I Introduction

An analytical tool called 'impact assessment' (IA) has taken centre stage in the preparation of legislation, rules and policies in the context of the EU over the last decade.[1] IA can be usefully described as a structured template guiding pre-political decision making with the aim of enhancing the amount and quality of information available on the impacts of various policy options. The template includes fixed analytical steps including a problem definition, a section dedicated to the setting of objectives, the articulation of policy options, the actual assessment of impacts, a comparison of the options on the shortlist and a proposed arrangement for monitoring and evaluation. An important additional goal of the tool is to improve

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[1] A.C.M. Meuwese, *Impact Assessment in EU Lawmaking* (Kluwer Law International, 2008); C. Cecot, R.W. Hahn, A. Renda and L. Schrefler, 'An Evaluation of the Quality of Impact Assessment in the European Union with Lessons for the US and the EU', (2008) 2 *Regulation & Governance* 405; A. Alemanno, 'The Better Regulation Initiative at the Judicial Gate: A Trojan Horse within the Commission's Walls or the Way Forward?' (2009) 15 *European Law Journal* 382.

accountability of the entire decision-making process by making this information public in a structured and accessible way so that stakeholders become aware what trade-offs decision makers are thought to be facing.[2] Motives for increasing reliance on impact assessment typically hinge on the possibility to improve 'consultation' processes by linking them to IA,[3] on capacities for 'control' over the regulatory process and on a broader set of 'quality' arguments—sometimes encompassing quantitative considerations.[4]

When the European Commission introduced IA in 2001, this was done in the context of the preparation of its legislative and policy proposals in order to address a series of criticisms about the quality of existing legislation and the way in which the Commission exercised its right of initiative.[5] After initial reluctance, the scope of the Commission's impact assessment system has gradually been extended so as to include *inter alia* those acts adopted by the Commission in the exercise of the delegation of its implementing powers.[6] Significant attention has been paid to this crucial area of EU decision making—traditionally known as 'comitology'—in the aftermath of the wave of procedural reforms designed to implement Articles 290 and 291 TFEU that followed the entry into force of the Lisbon Treaty.[7] Yet, the use of impact assessment is usually not considered as part of the set of possible accountability mechanisms that could curb 'new comitology.'[8] This article fills this gap in the literature by addressing the broader conceptual questions 'what is and what should be the role for IA in EU non-legislative rulemaking (hereinafter "rulemaking IA")?' These questions are all the more pressing since, although the Commission is progressively including the preparation of non-legislative measures in its impact assessment practice, it has not yet clarified the essential parameters.

This article proceeds as follows. Part II (the whys) traces why the IA requirement has been gradually been extended to delegated acts and implementing measures in the light of the emerging practice on this front. Part III (the hows) moves to discuss how IA could be performed when conducted on non-legislative acts and, equally important, how it is incorporated into the new procedures emanating from Articles 290 and 291 TFEU. In part IV (the whats), we identify different roles that IA might be called to play in EU rulemaking, exploring the three aforementioned drivers for the use of IA: 'consultation,' 'control' and 'quality.'

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[2] European Commission, Communication on Impact Assessment, COM(2002) 276 final, 3.

[3] J.M. Mendes, *Participation in EU Rulemaking. A Rights-Based Approach* (Oxford University Press, 2011), at 100, 106.

[4] See C.M. Radaelli and F. De Francesco, 'Regulatory Impact Assessment', in R. Baldwin, M. Cave and M. Lodge (eds), *The Oxford Handbook of Regulation* (Oxford University Press, 2010), at 279.

[5] Mandelkern report and Report of the Working Group on Better Regulation (Group 2c), May 2001, 21.

[6] Commission Legislative and Work Programme 2008, COM(2007) 640 final.

[7] S. Peers and M. Costas, 'Accountability for Delegated and Implementing Acts after the Treaty of Lisbon', (2012) 18 *European Law Journal* 427; P.P. Craig, 'Delegated Acts, Implementing Acts and the New Comitology Regulation', (2011) 36 *European Law Review* 671; B. Driessen, 'Delegated Legislation after the Treaty of Lisbon: An Analysis of Article 290 TFEU', (2010) 35 *European Law Review* 837; P. Craig, *The Lisbon Treaty, Law, Politics and Treaty Reform* (Oxford University Press, 2010), Chs 2, 7; R. Schütze, '"Delegated" Legislation in the (New) European Union: A Constitutional Analysis', (2011) 74 *The Modern Law Review* 5, 661–693; H. Hoffmann, 'Legislation, Delegation and Implementation under the Treaty of Lisbon: Typology Meets Reality', (2009) 15 *European Law Journal* 482.

[8] Peers and Costas (2012).

II The Whys: Applying IA to EU 'Rulemaking'

In this section, we describe how the scope of application of impact assessment within the Commission has progressively—if hesitantly—been extended so as to comprehend an increasing number of EU initiatives.

A The General Framework of IA in the EU

When IA was first introduced, it was taken by some as a potential source of 'Americanization' of the European administration.[9] In the United States, 'regulatory impact assessments'—the term most commonly used internationally—are only carried out for implementing rules (ie regulatory measures which further specify legislation previously adopted by Congress) by way of compensation for delegation of rulemaking powers and are as such hotly debated in the administrative law literature.[10] In the EU by contrast, IA initially applied to policy-related and legislative proposals only. It is significant for the current challenge to adapt IA to the rulemaking context that the European IA practice has been developed in the context of this particular type of delegation: 'original' delegation through the Treaties. Although IA could be perceived as a guarantee that powers are exercised in line with the limits and objectives of the power-conferring act (ie the Treaties),[11] the tool had to be adapted.

Being presented as an 'aid to the legislator',[12] the average IA consists of a combination of a quantitative socio-economic calculus and a more qualitative assessment which typically involves a degree of political judgment.[13] Keen to avoid getting enmeshed in the American debate on the desirability of cost-benefit analysis as a tool for decision making, the Commission has always emphasised the procedural improvements its IA regime has realised in its pre-legislative activities. Deviating somewhat from the origin of the tool, impact assessment is being presented as a means of achieving more relevant input in consultation processes, and only in the second instance as a tool aimed at conditioning regulatory action to a positive cost-benefit balance.[14] Moreover, because the IA reports containing the findings of the analytical work carried out by the Commission services are published—usually together with the proposals that were the subject of the analysis[15]—stakeholders can benefit from a 'body of evidence' that was previously not available. According to an inter-institutional agreement and a 'common approach' the European Parliament (EP) and the Council are committed to use the analytical findings of the Commission and to

[9] See, eg R. Hoppe, 'Ex Ante Evaluation of Legislation', in J. Verschuuren (ed.), *The Impact of Legislation, A Critical Analysis of Ex Ante Evaluation* (Martinus Nijhoff Publishers, 2009), at 88–89.

[10] See, eg J.B. Wiener and A. Alemanno, 'Comparing Regulatory Oversight Bodies across the Atlantic: The Office of Information and Regulatory Affairs in the US and the Impact Assessment Board in the EU', in S. Rose-Ackerman and P.L. Lindseth (eds), *Comparative Administrative Law* (Edward Elgar, 2010), at 309.

[11] P.P. Craig and G. De Búrca, *EU Law: Text, Cases and Materials* (Oxford University Press, 5th edn, 2011), at 99.

[12] COM(2002) 276 final, 3.

[13] For a similar perspective coming from the US, S. Shapiro and C. Schroeder, 'Beyond Cost-Benefit Analysis: A Pragmatic Reorientation', (2009) 32 *Harvard Environmental Law Review* 433, 450–459.

[14] European Commission, IA Guidelines 2009, SEC(2009)92, 47.

[15] In few instances, the publication of the IA may indicate that the legislative initiative has been aborted. See, eg the envisaged directive on the cross-border transfer of registered office that was withdrawn when the IA showed that 'no action' was the most proportionate response, SEC(2007)1707.

perform an IA on their 'substantive' amendments to the Commission's proposal.[16] As a result, IA is susceptible to play a role as an analytical support tool, not only for the co-legislators and interest groups but also for national parliaments—in the context of the yellow and orange card procedures—and even the EU courts.[17]

This procedural approach reflects a reticence to present IA as a 'control' instrument. This attitude clearly surfaced in 2005 when the European Commission established the Impact Assessment Board (IAB), an internal quality control body tasked to monitor the quality of the draft IA with limited formal powers at its disposal.[18] The relatively favourable appraisals of the IAB's record seem to be related to its practice of systematically publishing all its opinions dealing with individual draft IA reports.[19]

B Initial Reluctance to Applying IA to EU Non-Legislative Rulemaking

The reasons why the Commission hesitated so long to systematically include initiatives that are not of a 'legislative' or 'policy' nature are rooted in the way in which the IA practice developed within the Commission. IA started as a pilot project involving a few 'major' proposals in 2002 and as of 2005 became connected to the Commission Legislative and Work Programme (CLWP, now called the Commission Work Programme, or CWP),[20] the Commission's main planning instrument. Under current practice, the commitment by the Commission services to carry out an impact assessment is first expressed in a so-called 'Roadmap,' which can be found in an annex to the CWP. Although defining the scope of application of IA remains a Commission prerogative, requiring an IA for all initiatives in the Work Programme for some time provided a formal—if circular—argument against applying IA to comitology measures as the latter are not required to be included.

Another argument typically invoked to reject 'rulemaking IA' is linked to the nature of the policy initiatives generally subject to this sort of prospective scrutiny. The original system being designed for early stage assessment of broad initiatives, this would not be adapted to the inherently detailed and technical comitology decisions which are often severely limited by the authorising instrument. In particular, this makes it difficult—if not impossible—to include the option of 'doing nothing,'

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[16] Common Approach to Impact Assessment (2005)—European Commission, European Parliament and Council of Ministers, 'Inter-Institutional Common Approach to Impact Assessment' (Brussels, 2005); Inter-Institutional Agreement on Better Lawmaking (2003)—European Commission, European Parliament and Council of Ministers, 'Inter-Institutional Agreement on Better Lawmaking', *OJ* 2003 C 321/01 (Brussels, 2003).

[17] A. Alemanno, 'A Meeting of Minds on Impact Assessment: When Ex Ante Evaluation Meets Ex Post Judicial Control', (2011) 17 *European Public Law* 201. In the following cases impact assessment featured as part of the proportionality review: Case C-58/08, *Vodafone Ltd and Others v Secretary of State for Business, Enterprise and Regulatory Reform* [2010] ECR I-4999; Case C–176/09, *Luxembourg v European Parliament/Commission* [2011] ECR I-0000.

[18] A. Alemanno, 'Quis Custodet Custodes dans le cadre de l'initiative "Mieux légiférer"?' Une analyse des mécanismes de surveillance de la qualité réglementaire au sein de la Commission européenne et le Comité d'évaluation des analyses d'impact, (2008) 1 *Revue du Droit de l'Union Européenne* 43.

[19] European Court of Auditors, *Impact Assessments in the EU Institutions: Do They Support Decision-Making?* Special report No 3/2010 (Luxembourg: Publications Office of the European Union, 2010).

[20] Green Papers, Social Dialogue measures, and 'convergence-type' reports have always been exempted, as have periodic Commission decisions and reports, proposals following international obligations and Commission measures deriving from its powers of controlling the correct implementation of EC law and executive decisions. See European Commission, IA Guidelines 2005, SEC(2005) 791 and COM(2002) 276 final.

normally an essential requirement of the IA template.[21] A related issue is that the Commission from the start has been keen to make the EP and Council responsible for carrying out their own IAs when amending proposals. The Commission wanted to avoid the image of a technocratic provider of economic analyses to be supplemented at the request of the other institutions.[22] A strong focus on legislative acts was deemed to serve this goal better.

A further argument generally raised to question the appropriateness of extending IA to non-legislative acts is that such a use of IA, by slowing down the process, could undermine the efficiency—and in the long term ossify—their underlying procedures. It is undisputed that an automatic extension of the IA assessment procedures as they are currently applied to the legislative proposals might delay the adoption of non-legislative acts given the significant timeframes they foresee: 12 weeks consultation; 52 weeks for IA preparation; 8–12 weeks for IAB examination.[23]

Yet, as we will show below, the European Commission came to accept that it had to address the growing criticism regarding the exclusion of comitology measures from IA, and the only way to do this was to gradually widen the scope of IA.

C Widening the Scope of Application

Performing IAs on initiatives outside of the Commission's Work Programme has been possible, on a 'case-by-case basis,' since the adoption of the IA Guidelines of 2005.[24] However, discontent stemming from the lack of consistent coverage of all significant proposals led the external evaluators of the EU IA system to discuss the scope of application in their final report. This discussion reveals a wish on the part of the EP and Council to have certain comitology measures undergo an IA, 'especially since some [interviewees] are under the impression that the Commission is putting more and more significant policy decisions into such decisions.'[25] For the EP, lack of parliamentary control in the original comitology process has been an important reason to campaign for an expansion of the scope of IA. The Doorn report recommended 'to ensure that legislation adopted under the comitology procedure is submitted to an impact assessment [, as this] guarantees the quality of legislation and creates greater transparency in this process, which is not subject to parliamentary control.'[26] Furthermore, repeated requests from industry representatives for an extension of the IA system to comitology decisions, including technical updates to existing legislation, were reported.[27]

It became clear that the tide was turning when the Work Programme for 2007 mentioned that IA may be carried out for items which did not feature in the Work Programme and that the 'modalities for selection of these additional items will be

[21] IA Guidelines 2009, 24.

[22] A.C.M. Meuwese, 'Inter-institutionalising EU Impact Assessment', in S. Weatherill (ed.), *Better Regulation* (Hart Publishing, 2007), at 287.

[23] Part III—Annexes to IA Guidelines 2009, 7–9.

[24] IA Guidelines 2005, 6.

[25] The Evaluation Partnership, Evaluation of the Commission's Impact Assessment System (TEP Evaluation), (2007), 31.

[26] Doorn report 2006, explanatory statement, 7.

[27] TEP Evaluation, referring to Cp. Alliance for a Competitive European Industry, 2005: From Guidelines to Practice: An Industry Stakeholder Viewpoint. Alliance Comments on Commission's Impact Assessment Guidelines; and UNICE 2005: Evaluating the Community Impact Assessment Model.

established in the context of the creation of the new impact assessment support and quality control function which will work under the direct authority of the President.'[28] Around the same time some unforeseen, 'non-work programme' IAs were performed for acts subject to comitology procedures.[29] In 2007, the president of the Commission conceded that while the approach of tying the IA requirement to the Work Programme 'provided necessary discipline in the first years of setting up the system, it does not necessarily ensure optimal use of resources or systematic assessment of all proposals with the most significant impacts.'[30] According to the same communication, '[n]on-work programme and comitology items may have significant potential impacts, and the Commission is frequently faced with requests from Member States and stakeholders that impact should be assessed for such initiatives.'

In 2008, the Secretary-General of the European Commission announced that it was ready to widen the scope of IA beyond the initiatives listed in the Work Programme to systematically cover items with potentially significant impacts, 'including selected comitology items.'[31] The change was linked to the wish on the part of the Commission to focus impact assessments more on 'legislative proposals'—in the sense of 'proposals containing rules'—as opposed to 'policy items.'[32] This reflects an acceptance on the part of the Commission that 'rulemaking' may require an IA analysis exactly *because of* the likely interventionist nature of the measures involved. As a result, the Commission itself nowadays appears to be embracing a more detailed model of IA capable of doing justice to the complexity of individual, specific policy initiatives and their implementing measures. Moreover, while the inherent technical nature of an implementing act might appear a *prima facie* obstacle to subjecting it to an IA, this does not seem the case for delegated acts, ie acts of general nature amending or supplementing certain non-essential elements of a legislative act.

The 'delay' and 'ossification' arguments that were often used to resist 'rulemaking IA' also turned out to be less convincing in practice. First, the preparation time for a non-legislative act varies from a few days to several months and, second, the preparation of an IA of a non-legislative act is not automatically subject to the conventional IA timeframes.[33] A related counter argument that served to weaken the Commission's objections to extending IA to rulemaking was the growing importance of the concept of the 'proportionate level of analysis.' This concept—formerly referred to as a 'principle'[34] and as a result easily confused with the proportionality principle—was developed specifically in the context of the IA framework to 'avoid unnecessary effort

[28] 2007 Work Programme, COM(2006) 629 final, 4–5.

[29] DG Sanco was the frontrunner, see Meuwese (2008), 171–172.

[30] 'Better Regulation and Enhanced Impact Assessment', Information note from the President to the Commission, Brussels, 19 June 2007, SEC(2007) 926.

[31] C. Day, 'Enhancing Impact Assessment. Closing speech by Catherine Day, Secretary-General of the European Commission', European Commission Impact Assessment—Discussion with Stakeholders (Brussels, 2007). The stance was confirmed in the Second strategic review of Better Regulation in the European Union, COM(2008) 32 final and the Third strategic review of Better Regulation in the European Union, COM(2009)15 (28 January 2009), 6. The new IA scope was also codified in IA Guidelines 2009, 6.

[32] *ibid.*, 7.

[33] See, eg Roadmap on proposal for adoption of security scanner (Amendments to Commission Regulation (EC) 272/2009 (PRAC), Commission Regulation (EU) 185/2010 and Commission Decision 2010/774/EU) and IAB opinion on SEC(2011) 1328.

[34] IA Guidelines 2005, 16–19.

that would not lead to further insights or alter the conclusions or their robustness.'[35] In other words, it is perfectly acceptable to present a shorter IA, as long as the depth of the analysis is appropriate given the complexity of the problem at hand.

Thus, after a few years of sporadic practice, 'rulemaking IA' gradually expanded from 2009 onwards.[36] In its 2009 annual report, the IAB mentioned that for the first time, the share of CLWP items had fallen, while the number of impact assessments on catalogue and comitology items had increased.[37]

D Current Application of IA to Delegated and Implementing Acts

Decoupling the IA requirement from the Work Programme had the advantage that it was no longer possible for directorate-generals (DGs) to avoid the obligation to carry out an IA by keeping items off the Programme. Yet, out of abandoning this formal selection criterion, the need arose to identify an alternative substantive criterion. The new set of IA guidelines from 2009, which loosened the link with the CWP even further, do not include selection criteria other than a statement that '[i]n general, IAs are necessary for the most important Commission initiatives and those which will have the most far-reaching impacts.'[38] The chicken-and-egg causality problem is apparent here: one can only really have an idea about the need for an IA *after* that assessment has been carried out.

The Commission attempts to solve this conundrum through a procedural approach: the scope of application of IA is to be decided each year by the 'Secretariat General/ Impact Assessment Board and the departments concerned.'[39] To this end, DGs prepare the aforementioned Roadmaps, which consist of preliminary impact statements summarising the results of preliminary impact screening and setting out the planned IA and consultation work. They play an important role in the '[c]ase-by-case screening by the Secretariat-General in discussion with services decides which initiatives should undergo IA.'[40] Roadmaps provide an opportunity for stakeholders—including institutional stakeholders—to influence the direction and intensity of the analysis. Roadmaps are published in an annex to the CWP with a special heading reserved for 'Initiatives outside Commission work programme.' Since November 2011, a new email alert service with information about newly published roadmaps has been available for stakeholders registered in the joint Commission/Parliament transparency register.

The implementation of Article 290 and Article 291 TFEU remains a matter of work in progress and—as a result—the production of non-legislative acts that have been

[35] IA Guidelines 2009, 13.

[36] Impact Assessment Board, Report for the year 2010, SEC(2011)126; Impact Assessment Board, Report for the year 2011, SEC(2012)101,13: 'The Board also reviewed some IA reports accompanying proposals for delegated and implementing acts likely to have significant impacts.' According to TEP Evaluation 2007, 32. DG Internal Market had also started early to assess Comitology measures likely to have significant political, socio-economic or other major impacts.

[37] Impact Assessment Board, Report for the year 2009, SEC(2009) 1728. Interestingly, the IAB reported to have scrutinised four comitology items as far back as in 2007, as well as nine in 2008 and 13 in 2009.

[38] IA Guidelines 2009, 6.

[39] *ibid.*

[40] IAB report 2011. Previously, the IAB had the power to issue 'prompt letters,' urging DGs to carry out an IA where this is not foreseen (Art 6 of the former Rules of Procedure), but this power has been scrapped in the new Rules of Procedure without any explanation.

formally adopted as 'implementing measures' and 'delegated acts' is still only starting up. Only a few of these acts were subject to a formal IA.[41] Due to the automatic alignment as of 1 March 2011 of all but one comitology procedures (ie regulatory procedure with scrutiny (PRAC))[42] to the procedures enshrined in the new Comitology Regulation, a considerable number of implementing measures have already been adopted. The adoption of a delegated act, unlike that of an implementing measure, requires the adoption of a legislative act ('basic act') foreseeing and framing the possibility to adopt a delegated act. As a result, out of the several dozen legislative acts that have conferred the power to adopt delegated acts on the Commission, only five have led the Commission to formally adopt delegated acts.[43] This explains why—at the time of writing—there are more instances of IA performed on implementing measures than on delegated acts. However, looking at the overall number of IA performed on implementing measures it becomes clear that only few of them have been subject to formal IA in accordance with the guidelines. Instead, it seems that the Commission often engages in 'informal IA,' consisting in a broader consultation process through which the Commission services receive comments upon a draft implementing measure, rather than formally preparing an IA for that act. Since these forms of informal assessment escape the Roadmap screening by the Secretariat-General and therefore also the review by the IAB, they cannot easily be identified. Our analysis in the next section is thus limited to the few instances of formal IA performed on draft delegated acts and draft implementing measures.

III The Hows: Developing the Practice of 'Rulemaking IAs'

Carrying out an IA on a proposed non-legislative act inevitably implies engaging in a different type of analysis compared to that performed in the original IA. This is true for at least three reasons: first, the problem to be addressed through the act under examination most likely will have evolved from the problem examined in the basic act. This implies a need for engaging in fresh scrutiny of the policy options envisaged to implement or exercise the delegation of powers contained in the basic act. Second, the non-legislative measures, regardless of whether they are implementing measures or delegated acts, typically add something to the basic act. This is clearly the case for

[41] The Commission's IA website (http://ec.europa.eu/governance/impact/index_en.htm) contains lists of all published impact assessments per year, which contain references to the proposal title and clickable proposal numbers. These are the lists we consulted while preparing this article.

[42] This is the Regulatory Procedure with Scrutiny (RPS), also known in English by its French acronym—Procédure de Réglementation avec Contrôle (PRAC). This additional procedure, as enshrined in Art 5a of the modified 1999 Comitology Decision, was an explicit response to a number of the Parliament's claims concerning its involvement in the delegation of powers to the Commission. Under the new regime, the PRAC is set to apply until it will be replaced by the procedure for delegated acts. Although this shall occur by the end of 2014, the Commision committed to do so by the end of 2012.

[43] See, eg Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, *OJ* L 304, 22.11.2011, 18–63; Directive 2010/73/EU of the European Parliament and of the Council of 24 November 2010 amending Directives 2003/71/EC on the prospectus to be published when securities are offered to the public or admitted to trading and 2004/109/EC on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market, *OJ* L 327, 11.12.2010, 1–12; Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, *OJ* L 174, 1.7.2011, 74.

delegated acts insofar as they 'amend or supplement non-essential elements of the legislative acts.'[44] Third, the basic act, having determined the principles and the policy choices of regulatory action, inevitably constrains—regardless of whether it confers on the Commission delegation or implementing powers—the scope and nature of the analysis.

Despite these clear differences, the IA Guidelines offer only limited guidance on how to perform 'rulemaking IA.' This document, still in pre-Lisbon terminology, state that 'in an IA for a comitology decision you should not repeat the analysis of the IA for the basic legislation (if it exists) but, rather, focus on the actual decision at stake'[45] and that 'the IA of a comitology decision might focus on operational objectives, because general and specific objectives will already have been formulated in the IA for the legislation on which the comitology process is based.'[46] Furthermore, in a table which distinguishes between different focus points for IAs on different types of initiatives, it is stated that for 'comitology decisions' 'IA should focus on:

- identification of specific and operational objectives, linked to the objectives/requirements of the basic legislation;
- subsidiarity and proportionality analysis to explain the necessity and added value of EU action;
- options should include non-legislative action (short analysis of feasibility) and different implementation modes and/or technical detail of envisaged Commission decision (Consideration of whether "doing less" is possible);
- thorough assessment of impacts in relation to specific and operational objectives, taking full account of relevance of technical detail and using quantification to the extent possible; and
- monitoring and evaluation provisions should include concrete indicators reflecting specific and operational objectives.'[47]

The Guidelines also recommend that:
'IA should avoid excessive effort on:

- description of policy context/constraints and general objectives; and
- assessment of impacts in relation to general objectives of basic legislation or wider EU-policies.'

Besides being quite obvious, these indications clearly fall short of addressing an important set of questions posed by 'rulemaking IA.' Thus, to what extent should an IA for a non-legislative act be subject to the same procedures, timeframes, methods as an IA for a legislative proposal (A)? What kind of relationship should exist between the IA performed on the basic act and the one carried out on the ensuing non-legislative act? And to what extent, and in which circumstances, does the basic act mandate and/or shape the kind of IA to be conducted (B)? What role, if any, should the IAB play in the review of the draft IA of a non-legislative act (C)?

[44] Craig 2011, at 674.
[45] 2009 IA Guidelines, 15.
[46] 2009 IA Guidelines, 27.
[47] *ibid.*

A IA Procedure for Non-Legislative Acts

The 2009 IA Guidelines—as they precede the reform that led to the introduction of non-legislative acts as enshrined in Articles 290 and 291 TFEU—provide very limited guidance on how to carry out an IA of those acts. One might therefore expect to find more elements in the documents implementing the procedures for adopting delegated and implementing acts. Yet both the Common Understanding and the new Comitology Regulation are silent when it comes to determine how to incorporate IA to their respective procedures. In these circumstances, it might be presumed that these procedures, including their timeframes, methods and institutional mechanisms, automatically extend to and govern the preparation of IA of delegated acts and implementing measures. This would be in line with the Commission's long-standing wish to have one uniform procedure and framework for all 'impact assessment activities.' A brief excursus on the few IAs performed on non-legislative acts confirms that the Commission has been resorting to the general procedure, at least by way of default. Looking at the preparation of delegated acts, all IA performed so far on draft delegated acts have not only been prepared in line with the 2009 IA Guidelines but they have also been scrutinised by the IAB.[48] For instance, this is the case for the delegated act adopted in relation to the Amended Prospectus Directive.[49] In a move that is perhaps a slight deviation of standard procedure, in view of the preparation of the impact assessment of the delegated acts foreseen by their respective basic acts, the Commission services have solicited external IAs in order to obtain 'clear recommendations as to how the act should be framed and . . . the necessary supporting analysis and evidence for its conclusions.'[50] If anything, it seems that the Commission's idea that the IA and the proposal should be designed simultaneously is taken more seriously in 'rulemaking' than in the legislative context. Thus, for instance, when preparing the delegated act on the detailed rules for a unique identifier for medicinal products for human use, the Commission services have published a 'concept paper' 'with a view to preparing both the impact assessment and the delegated act.'[51] As for the future, among the newly published Roadmaps, there are quite a few entries regarding delegated acts, for instance the intended Commission Delegated Act specifying certain elements of the regulation on short selling and certain aspects of credit default swaps.[52] The Roadmap for this latter initiative mentions *inter alia* that the IA work has already begun and that the 'existing impact assessment'—presumably the one prepared for the basic act—will be used.

When it comes to implementing measures, it seems more difficult for the Commission to follow a rigorous IA regime insofar as draft implementing measures 'in the

[48] The lists of published IAs on the Commission's dedicated web site (see note 41) also contain a link to the IAB opinions, thereby making it easy to verify whether a draft IA report has been reviewed by the Board.

[49] Impact Assessment accompanying the Commission Delegated Regulation amending Regulation (EC) No 809/2004 as regards the format and the content of the prospectus and base prospectus, of the summary and of the final terms and the disclosure requirements, SWD(2012) 77 final.

[50] See, eg RAND, Bringing online in line: Contribution to an Impact Assessment for the Delegated Act to implement the online provisions of the revised Energy Related Products Directive; CEES, Study on the Impact of the Prospectus Regime on EU Financial Markets, Final Report, June 2008.

[51] Concept Paper, Sanco.ddg1.d.6(2012)73176, Brussels, 20/01/2012, 3, and see also the Roadmap for the impact assessment available.

[52] Roadmap on a Commission Delegated Act specifying certain elements of the Regulation on short selling and certain aspects of Credit Default Swaps, January 2012.

pipeline' traditionally escape formal planning mechanisms such as the CWP. Certain DGs maintain a 'comitology planner,' but it appears to have been impossible to implement such a mechanism across services. The lack of overview combined with the sheer quantity of measures may cause the Commission to resort to an 'informal IA.' However, once the draft implementing measure is earmarked as 'impact assessment planned.' the Commission services—in line to the 2009 IA Guidelines—submit the draft IA to the IAB. One example is the IA completed for the Commission Regulation implementing Directive 2005/32/EC with regard to eco-design requirements for simple set-top boxes,[53] as well as its twin, the IA for the Commission Regulation implementing Directive 2005/32/EC with regard to household refrigerating appliances.[54] While the commitment undertaken in 2010 to prepare roadmaps for all initiatives which may have significant impacts (not only for CWP items but also for Catalogue and Comitology items) makes it easier to enforce the standards once an item has been earmarked for 'formal' IA activity, it does not solve the selection problem.[55]

Apart from legal certainty issues, the approach for selecting items to undergo IA is particularly unsuitable for implementing measures because of their sheer quantity and tendency to escape all central planning mechanisms. The role of Roadmaps in identifying initiatives that need lighter and more intense forms of impact analysis, specifically in the preparation of implementing measures, is worth developing further. More critically, it is a missed opportunity that—even though the extension of IA to non-legislative acts occurred at the same time of the Lisbon reforms—none of the measures implementing Articles 290 and 291 TFEU took care of incorporating IA into their new procedures. Although it is true that Article 290 TFEU—unlike Article 291—does not call for the adoption of rules for its implementation,[56] it does require—as demonstrated by the Common Understanding—the production of a framework regulating the preparation and adoption of a delegated act. In the light of the above, it is regrettable that neither the Common Understanding nor the new Comitology Regulation addresses the procedural and substantive challenges of rule-making IA. This could have been done by providing a set of clear rules governing its operation in relation to both categories of non-legislative acts. By increasing accessibility and transparency of 'rulemaking IA,' these rules would have benefited not only institutional actors but also stakeholders.

B IA of Basic Act vs IA of Non-Legislative Act

The relationship between the IA performed on the basic act in the past and the IA to be carried out on the draft non-legislative act depends on how the basic act confers authority to the Commission as well as to the extent to which that document provides guidance on how to perform an IA.

Any basic act, regardless of whether it confers delegated or implementing authority on the Commission, tends to frame the exercise of the Commission's powers.[57] However, this framing activity largely varies not only between delegated and implementing acts but also within each of these categories. In the case of delegated acts,

[53] SEC(2009)114.
[54] C(2009)582.
[55] IAB report 2009, 5.
[56] Peers and Costa (2012), 441.
[57] Craig 2011, 674.

Article 290 TFEU mandates the legislator to explicitly define in the basic act 'the objectives, contents, scope and duration of the delegation of power.' In order to do so, the Commission, Council and the Parliament agreed, in their common understanding, 'to refer as far as possible to the standard clauses. . . when proposing or making delegations of power under Article 290 TFEU.' In line with this document, most of the legislative acts conferring delegated powers generally do so by relying on one of those standard clauses. However, there are instances in which the co-legislators not only departed from the standard clauses but also determined the procedure to be followed for the preparation of draft delegated acts. For instance, all four financial services directives specifically direct the Commission to have the draft delegated acts to be prepared in the first place by a specialised agency. They also indicate that—by departing from the usual two-month review period[58]—the EP and Council only have one month, with a possible one-month extension. Although these provisions do not have a direct influence on the way in which the IA report is performed, they illustrate how the basic act may often frame the modalities of adoption of the delegated act. Against this backdrop, it should come as no surprise that there are instances in which the basic delegating act provides specific guidance to the Commission services on how to perform the IA of the draft delegated act. For instance, Article 11(3) of the recast Energy Labelling Directive mandates that:

> In preparing a draft delegated act the Commission shall: Take into account those environmental parameters . . . ; Assess the impact of the act on the environment, end-users and manufacturers, (. . .); Carry out appropriate consultation; Set implementing dates (. . .) taking into account (. . .) possible impacts on SMEs or on specific product groups manufactured primarily by SMEs.[59]

Interestingly, although this directive does not explicitly refer to the formal IA framework, it contains a 'built-in' requirement by the EU legislator to actually perform such an IA. In these circumstances, it is submitted that the guidance contained in the basic act operates like a *lex specialis vis-à-vis* the 2009 IA Guidelines which represent the default regime. Moreover, virtually all legislative acts providing for the delegated act procedure recommend the Commission services to systematically consult national experts and to 'conduct any research, analysis, hearings and consultations required.'[60] As indicated above, the Commission appears to have taken this recommendation seriously in the adoption of its first delegated acts.

Similarly, the preparation of implementing measures, and in particular the preparation of IA of these acts, may be framed by the basic act to a greater or lesser extent. Also, some basic acts conferring implementing powers on the Commission expressly require not only the performance of an impact assessment but also the application of a set of criteria.[61] Although adopted prior to the new rules on delegated and implementing acts took force, the Ecodesign Directive provides an example of how basic acts can tightly structure subsequent impact assessment activities. Its Article 15 mandates *inter alia* that:

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[58] Common Understanding, para 10.

[59] Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products, OJ L153 2010.

[60] Peers and Costa 2012, 453.

[61] See, eg Art 26 (country of origin labelling) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, OJ L 304, 18–63.

> [i]n preparing a draft implementing measure the Commission shall:
> (a) consider the life cycle of the product and all its significant environmental aspects, inter alia, energy efficiency. The depth of analysis of the environmental aspects and of the feasibility of their improvement shall be proportionate to their significance . . . ;
> (b) carry out an assessment, which shall consider the impact on the environment, consumers and manufacturers, including SMEs, in terms of competitiveness—including in relation to markets outside the Community—innovation, market access and costs and benefits;
> (c) take into account existing national environmental legislation that Member States consider relevant;
> (d) carry out appropriate consultation with stakeholders;
> (e) prepare an explanatory memorandum of the draft implementing measure based on the assessment referred to in point (b); and
> (f) set implementing date(s), any staged or transitional measure or periods, taking into account, in particular, possible impacts on SMEs or on specific product groups manufactured primarily by SMEs.[62]

However, as in the case of delegated acts, the level of precision varies greatly from one basic act to another.

C The Role of the IAB in 'Rulemaking IA'

The IAB mandate, as it has recently been revisited, unmistakeably provides competence to the Board to also examine those draft IAs carried out on non-legislative acts. Its scope of activity now states that '[t]he IAB will, as a priority task, examine all impact assessments, which accompany Commission initiatives with significant impacts (*including proposals of delegated and implementing acts*).'[63] The 2011 IAB Report confirms that '[t]he Board also reviewed some IA reports accompanying proposals for delegated and implementing acts likely to have significant impacts.'[64] However, these textual references do not suffice to clarify the exact role that the IAB is called to play *vis-à-vis* the draft IA of those acts. Subjecting a draft IA of a non-legislative act to the IAB does not boil down to a mere procedural requirement adding up 8–12 weeks to the overall preparation time. Rather, it implies a quality review of draft reports, which results in a recommendation for resubmission in 36% of opinions.[65] Indeed, although the practice is limited, a brief investigation shows that the IAB does not hesitate to exercise the same level of quality overview for 'rulemaking IA' as it does for IA regarding legislative acts or policy proposals.[66] The IAB also uses one and the same quality checklist for every type of impact assessment.[67]

IV The Whats: The Potential Impact of 'Rulemaking IA'

This section explores the broader consequences associated with increasing reliance on IA in procedures leading to the adoption of both implementing measures and delegated acts. In so doing it distinguishes among the effects regarding the use of

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[62] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products, *OJ* L 285/10, 10–35.

[63] IAB Mandate. No document number available, para 3, see http://ec.europa.eu/governance/impact/iab/docs/iab_mandate_annex_sec_2006_1457_3.pdf. Italics by authors.

[64] IAB Report 2011, 13.

[65] IAB Report 2011, 13.

[66] S. Gomtsian and A.C.M. Meuwese, 'Subsidiarity and Proportionality in the Impact Assessment Board's "case law"', paper prepared for the ECPR Regulatory Governance conference in Exeter, 27–29 June 2012.

[67] IAB report 2011, Annex 2: Impact assessment quality checklist template.

consultation (A), those regarding the institutionalisation of control over rulemaking procedures (B) and those regarding the quality of the measures (C).

A Enhanced Consultation

A firm practice of IA on rulemaking might enhance consultation at that stage of EU decision making. Consulting interested parties is indeed an obligation for every impact assessment: stakeholders should be able to comment on a clear problem definition, subsidiarity analysis, description of the possible options and their impacts.[68] Therefore, the Commission's choice to subject to IA draft non-legislative measures tends to encourage compliance with its own general principles and minimum standards for consultation of interested parties.[69] Moreover, the role of consultation within the EU IA system has strengthened over time. In particular, the Commission's compliance with the minimum standards of consultation appears to be increasingly enforced by the IAB. An example of the 'intensity' of IAB scrutiny on this issue is provided by the following statement contained in a recent Board opinion: 'Clarify how stakeholders were consulted and what they said. The report should provide more details upfront about how stakeholders were consulted and how a representative spread of views was ensured. It should be made clear whether any groups have strong views about any key issue or option.'[70]

B Enhanced Control

'Rulemaking IA' may also enable enhanced control over the exercise of delegated authority. As discussed above, the EP historically perceived IA on rulemaking as a quality guarantee as well as a compensation for the lack of parliamentary control on comitology. Concrete suggestions to expand the scope of the IA requirement to 'comitology' date from the same time that the Parliament discovered it as a potentially useful tool to influence the Commission's exercise of the right of initiative.[71] Now that enhanced parliamentary control over rulemaking has become a tangible reality, one may wonder whether an IA of a non-legislative act is still expected to play a 'controlling' role. The original idea voiced in the Doorn report, namely to use IAs to select committee decisions that should be subject to parliamentary approval, has not been taken up as such. Yet, it is reasonable to expect IA play some role in the exercise of the right of objection and the right of scrutiny. Under the delegated act procedure, both the EP and the Council may object to an individual delegated act on any grounds within two months from formal adoption by the College of Commissioners (right of objection). Under the procedure leading to the adoption of an implementing measure, both the EP and the Council may at any time indicate the Commission that they consider a draft implementing measure to exceed the implementing powers provided for in the basic act (right of scrutiny). One of the main novelties of the procedure for delegated acts is that, unlike what happens under the

[68] IA Guidelines 2009, 18.

[69] Towards a reinforced culture of consultation and dialogue—General principles and minimum standards for consultation of interested parties by the Commission, COM(2002) 704 final.

[70] IAB opinion on Impact Assessment of Commission Decision on determining transitional Community-wide rules for harmonised free allocation pursuant to Art 10a of Directive 2003/87/EC.

[71] See Meuwese 2008, at 100–125.

new Comitology Regulation, committees as they existed under the former comitology system no longer play a role. The Commission, in the preparation of a draft delegated act, is only bound to a commitment to 'carry out appropriate and transparent consultations (. . .), including at expert level.'[72]

Although we observe that in the preparation of delegated acts, the Commission tends to comply with this commitment, it is likely that its contact with the expert groups will be (even) less formalised than it was with the committees and that the outcome (studies, opinions, reports, etc) of these expert consultation will be (even) less available. In these circumstances, should the Commission services carry out a formal impact assessment, this document will offer a crucial source of information that otherwise would not be available to the Council, the EP as well as the public. A similar, potential effect of 'enhanced control' stemming from the use of IA may also play out *vis-à-vis* implementing measures. Indeed, although the procedure for the adoption of implementing acts maintains the consultation of committees, the EP could still benefit from having access to an IA. This is especially the case in the context of the right of scrutiny the EP maintains where the basic act is adopted under the ordinary legislative procedure.[73] The IA report may provide information that helps to assess whether the Commission has exceeded its implementing powers.

Last, but not the least, there is another type of control over rulemaking that IA may contribute to: judicial review. The mere availability of IA performed on non-legislative acts is likely to lead interested parties to refer to them when challenging the legality of those acts. As illustrated by the recent judgements in *Vodaphone*, *Afton* and *Luxembourg v Commission*,[74] the 'pre-legality check' contained in an IA, in particular in relation to the conformity of the proposal with the proportionality principle, may be invoked by the parties in front of the Court as procedural benchmark of legality.[75] It is submitted that such a judicial use of IA may enhance the control exercised upon rulemaking not only by the EP and the Council but also by the private parties.[76] This seems especially true since the General Court has recently clarified the scope of the new standing rules for actions brought by non-privileged applicants against 'regulatory acts.'[77] As the meaning of 'regulatory act' as enshrined in Article 263(4) TFEU must be understood as covering all acts of general application apart from legislative acts, we may expect more judicial review activity on 'non-legislative' rulemaking than in the past.[78]

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[72] Common Understanding, para 4. In particular, under the Commission Communication on the delegated act procedure (COM(2009) 673), the Commission commits to consult national experts and to (conduct any research, analysis, hearings and consultations required) on a draft delegated act.

[73] Art 11, Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

[74] Case C-58/08, *Vodafone Ltd and Others v Secretary of State for Business, Enterprise and Regulatory Reform* [2010] ECR I-4999; Case C-343/09, *Afton Chemical Limited* [2010] ECR I-7027; Case C‑176/09, *Luxembourg v European Parliament/Commission* [2011] ECR I-0000.

[75] K. Lenaerts, 'The European Court of Justice and Process-oriented Review', College of Europe, Research Paper in Law, 1/2012, 7.

[76] Alemanno (2011).

[77] See, eg Case T-18/10, *Inuit Tapiriit Kanatami v European Parliament and Council* [2011] ECR II-0000 and Case T-262/10, *Microban International and Microban (Europe) v Commission* [2011] ECR II-0000.

[78] See C. Buchanan, 'Long Awaited Guidance on the Meaning of "Regulatory Act" for Locus Standi Under the Lisbon Treaty', (2012) 3 *European Journal of Risk Regulation* 1, 115–122.

C Enhanced Quality

Effects in the realm of 'quality' are by definition hard to pin down. Instead of attempting to draw some general conclusions under this heading on the basis of a limited practice we recount an anecdote which illustrates how IA—in this case through the involvement of the IAB—can enhance the quality of the decision-making process. The supplementing and implementing measures on the use of security scanners at EU airports aim to enable airports and Member States wishing to use security scanners for screening passengers to do so under strict operational and technical conditions. Yet there were no EU-wide rules on whether passengers must be informed about the conditions under which the security scanner screening takes place, and, more importantly, on whether they should have been offered the right to opt out of this form of screening. In the draft IA report—carried out at the request of the EP—the Directorate-General for Mobility and Transport (DG MOVE) concluded that option 5 (no recognition of opt out from security scanners) examined in the IA was the preferred policy option because it guaranteed the 'best balance between meeting the objectives and achieving the best other policy impacts.'[79] The Impact Assessment Board in its first opinion questioned the evidence base leading the relevant DG to choose this option: 'the report should either provide more convincing—preferably quantitative—evidence to support the preference in the report's conclusions for option 5 over option 6 (recognition of an opt out from security scanners), or should state that the evidence is inconclusive to support a preference for either one of these.'[80] As a result of this first opinion, the resubmitted IA report—by taking stock of the IAB's suggestions—no longer expressed a preference for any of those two options but deliberately left the choice to the policymakers after having highlighted the relevant trade-offs:

> [w]hile option 5 would appear to be the best option from the perspective of efficiency and security, option 6 would offer the best protection of fundamental rights. The present impact assessment considers that both options are valid and that the trade-offs between them to be addressed by the political decision-makers.[81]

The final proposal, adopted by the Commission, corresponds to option 6, and allows passengers a choice. This anecdote confirms that IA can have a real influence in decision making regarding rulemaking too, as it flies in the face of the argument that non-legislative acts would be too technical in nature to be subject to a meaningful IA.

V Conclusions

At a time in which the Commission is progressively including the preparation of non-legislative measures in its impact assessment practice, this article discussed the 'whys, whats and hows' raised by this significant evolution of the EU impact assessment system. Although the Commission practice of 'rulemaking IA' is only in its infancy, our analysis leads to three main observations regarding the role for IA in EU non-legislative rulemaking.

First, the inclusion of non-legislative acts under the EU Commission's IA occurred gradually, despite the Commission's reticence and as a result of frequent requests by

[79] 2011 IAB Report, 24.
[80] SEC(2011)1328.
[81] SEC(2011)1327, 54.

not only the EP and the Council but also by the industry representatives. Although the rationale for such an extension is not expressly stated in any policy document, it seems that virtually all stakeholders perceive IA not only as a tool to improve the quality of the proposed act, by gathering more evidence, but also to create greater transparency and—as a result—easier access to the process leading to the adoption of the act.

Second, we observe a simultaneous harmonisation and juridification of standards and procedures occurring as a result of the extension of the IA procedure to rulemaking. The procedural harmonisation stems from the insistence on the part of the Commission—and by extension by the IAB—to bring 'rulemaking IA' within the regular IA framework. Any variation as to the focus and depth of the analysis must come from the presently underdeveloped concept of 'proportionate level of analysis.' In parallel to this harmonisation, we observe incipient juridification through the fairly detailed guidance on how to perform the specific IA in a particular instance of delegation of rulemaking power contained in certain basic acts.[82] This development could bring the European IA system a step closer to the American one, in which IA is primarily seen as an instrument for controlling delegation. At the same time, it seems that the Commission has not let go of its initial idea of IA as an instrument that strengthens consultation either, as is illustrated for instance by the use of Roadmaps for 'rulemaking IA.' The two objectives appear to be self-reinforcing rather than mutually exclusive.

Third, IA procedures seem especially appropriate for the adoption of delegated acts, whose procedure no longer assures—especially when compared with the previous PRAC procedure—a free flow of information originally produced by a committee of national representatives. Overall, our analysis points to a potential of IA to contribute to a more encompassing, higher quality and better controlled exercise of delegated authority. Unfortunately, as demonstrated above, EU law faces today a gap between the potential of IA in achieving those goals and its actual institutional embedding.

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[82] On the pros and cons of juridification of IA procedures in EU law, Alemanno (2011).

