Impact assessment in EU lawmaking

Meuwese, A.C.M.

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Anne Claartje Margreet Meuwese

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Referent:	prof. dr. P. Popelier (Universiteit Antwerpen, België)
Leden:	prof. dr. R.J.A. van Gestel (Universiteit van Tilburg)
	prof. dr. C.M. Radaelli (University of Exeter, UK)
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Voor opa Dolf
(1916 – 2007)

Preface

In the course of the four years working on this thesis I came up with various cover stories. To my hairdresser I would say my research was about 'red tape' from Brussels, to a fast-living consultant it was all about the Lisbon process – or so I claimed – and to a philosopher (I actually met a few) I would explain that my thesis dealt with legitimacy. In my own mind the mission had been clear when I first started to investigate the use of impact assessment in EU lawmaking: I would not only capture the first experiences with implementing impact assessment in the European legislative process, but also find out whether economic analysis of the consequences of legislation matters – and how. But in the course of the project this mission was both extended and narrowed down. I quickly discovered that EU impact assessment was not necessarily about a more rigorous use of economic analysis, at least not in any straightforward way. It was all about subsidiarity, procedural justice and inter-institutional power fights and as such it was 'the continuation of constitutional debate by other means'. This in itself was an interesting finding, but it also made it impossible to pin down the 'net effect' of the introduction of impact assessment when it was part of a fundamental struggle that was unlikely to be resolved any time soon.

While you try to shape the project, it also shapes you and your journeys. From Leiden it took me to Brussels for a five-month intermezzo as trainee at the unit Better Regulation and Institutional Matters of the European Commission's Secretariat-General. During this happy period in Spring 2005 I learnt so much, for instance how theoretical notions have practical implications and how practical decisions are harder to take without theoretical back-up. A few months after returning to my desk in Leiden the chance to experience interdisciplinarity first hand presented itself as a research job at the Politics Department of the University of Exeter. Here I discovered that the differences between political scientists and constitutional legal scholars were much greater than the overlaps in subject matter would suggest. 'Advancing socio-scientific knowledge through making causal inferences' is a long way from 'advancing the law' and I still do not understand the respective disciplines' fixations on either.

The stories on impact assessment accumulated, the angles multiplied and yet in the end it all had to turn into one book. The result is a detailed account of how all actors involved in EU lawmaking deal with impact assessment and

an argument about the trade-offs at the meta-level that need to be taken into account when reforming the current, malleable EU impact assessment system.

I would like to take this opportunity to thank the people whose unwavering support has helped me to just get on with it.

The first word of thanks is for my *paranimfen* and good friends Jacco and Zayènne. Jacco, I admire your intelligence, sense of humour and warmth and I am glad our friendship is still going strong. Zayènne, your passionate opinions as well as your professionalism were consistently refreshing during the trials and tribulations of PhD life. Our Florence trips even made thesis writing seem glamorous at times. Maris, despite the differences between us (many of them somehow related to the difference between a PhD in Astronomy and a PhD in Law) you are like family to me. It is great that we managed to spend so much time in Leiden together. Annelieke and Marieke have both provided almost permanent lifelines on many fronts, through Skype and in person. I would also like to extend words of thanks to other friends – old and new – who have hosted, fed, lectured, inspired and/or cherished me throughout the past years: Armando, Christien, Djordje, Emma, Felix, Frederik, Freya, Hristina, Ineke, Inge, Ivan, Julie, Lorna, Maja, Melissa, Michiru, Peter, Radostina, Simone and Sonja. Graciela at Waterside and Michelle & Robin at Bridge Cottages have been super-housemates (and great career examples) during my time in Exeter, speaking words of comfort to my pale face after I returned from another late night session at the office. I am grateful for the support that Marlies & Hendrik (who I often think is really my big brother) and Julia (who will always be my little sister but also the best travel companion ever) gave me. The warmest thanks are for my parents, Joost and Maria, to whom I owe everything.

The Department Constitutional and Administrative Law in Leiden has been an amazing place to work, not least because Ymre has been a wonderful office mate, and a safe haven even after I started working in Exeter. I am particularly thankful that the department awarded me a non-stipendiary fellowship which enabled me to continue writing my thesis in an efficient way and I would like to thank Tom Barkhuysen as head of department for this. Many thanks go to Lars Mitek-Pedersen for the faith he placed in me as a trainee, as well as to all the colleagues in the unit. Let me especially mention Eric Philippart and Craig Robertson, who taught me not only about the politics and practice of impact assessment, but also about the perils of academia. I would further like to thank all colleagues at the Department of Politics of the University of Exeter and particularly the colourful and inspiring team at the Centre for Regulatory Governance, with a special word of appreciation for my former office mate Frank. Although this PhD research was carried out completely separately from the European Network for Better Regulation (ENBR) and Evaluating Impact Assessment (EVIA) – the two projects funded by the EU Sixth Framework Programme that I worked on in Exeter – I would like

to thank the researchers in these projects for providing a sense of community in impact assessment research. Other people whose intellectual input into either parts of the thesis or its overall conception I gratefully acknowledge are Jim Dratwa, Chris Jetten, Tim Keyworth, Bronwen Morgan, Robert Scharrenborg, Frank Schiller and Helen Toner. One of the best parts of this research project has been sharing experiences with other young researchers I met at various conferences and summer schools, notably the CARR Graduate Conference at the London School of Economics, the Academy of European Law and the First NEWGOV-Connex training course at the European University Institute, the Advanced Colloquium on Better Regulation at the University of Exeter and the PhD network for European Commission trainees (thanks to Pauline Le More and Wim Weymans). The final word of thanks is reserved for the people I interviewed as part of the research for this thesis, whether on a formal or informal basis, for their cooperation and time.

Anne Meuwese
Exeter/Leiden

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List of abbreviations

BEST	Business Environment Simplification Task Force
BR	Better Regulation
BRE	Better Regulation Executive
BSE	Bovine spongiform encephalopathy
CAP	Common Agricultural Policy
CBA	Cost-benefit analysis
COSAC	Conference of Community and European Affairs Committees of Parliaments of the European Union
DBR	Directors and Experts of Better Regulation
DG	Directorate-General
ECJ	European Court of Justice
EEA	European Environmental Agency
EFSA	European Food Safety Authority
EO	Executive Order
EU	European Union
IA	Impact assessment
IAB	Impact Assessment Board
IIA	Inter-Institutional Agreement
iQSG	interservice Quality Support Group
ISC	Inter-Service Consultation
ISSG	Inter-Service Steering Group
JLS	Justice, Liberty and Security
JRC	Joint Research Centre
MEP	Member of European Parliament
MoU	Memorandum of Understanding
NAO	National Audit Office
OECD	Organization for Economic Co-operation and Development
OIRA	Office of Regulatory Affairs
OMB	Office of Management and Budget
OMC	Open Method of Coordination
REACH	Registration, Evaluation and Authorization of Chemicals
RIA	Regulatory impact assessment
SCM	Standard Cost Model
SLIM	Simpler Legislation for the Internal Market
SME	Small and medium enterprise
TEC	Treaty establishing the European Community
TEU	Treaty on European Union
TBT	Technical Barriers to Trade
UK	United Kingdom

US	United States
WP	Work Programme
WTO	World Trade Organization

I Introduction

> The constitutional reality of the EU is more than the 'grand bargains' negotiated at Intergovernmental Conferences.[1]

Constitutional norms can develop through other means than amendments to constitutional texts or – in the particular case of the European Union – Treaty amendments in accordance with to the procedure of Article 48 TEU. This phenomenon is well-known and hardly disputed among legal scholars: high-profile legal facts such as landmark court decisions or obligations stemming from international treaties can induce or even dictate constitutional change. More controversially, constitutional scholarship advocating constitutional pluralism has proposed to extend the realm of constitutional norms a bit further and recognise that in the current global order 'a range of different constitutional sites and processes configured in a heterarchical rather than a hierarchical pattern'[2] exist. However, the 'development of an explicit constitutional discourse' is still seen as indispensable for recognition as a constitutionally significant norm.[3]

But what happens if we set out to explore possible spaces for constitutional norm formation beyond 'a self-conscious discourse of constitutionalism'?[4] This idea has been elaborated by Colin Scott in *Regulating Law*, a book which aims to apply a 'regulatory lens' to law. His contribution argues that viewing constitutions as a form of 'regulation' has two advantages. It enables us to see better which norms and institutions might be fundamental to the control of public power and it allows for incorporating the regulation of privately exercised public power into constitutional theory.

This thesis takes up the challenge of exploring the grey zone between constitutional law and regulation but approaches the issue the other way around. A 'regulatory subject', namely the recently established EU impact assessment (IA) regime, is investigated as a possible source of constitutional norm formation and application outside of any explicit constitutional discourse.

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1 I. Eiselt and P. Slominski, 'Sub-Constitutional Engineering: Negotiation, Content, and Legal Value of Interinstitutional Agreements in the EU' (2006) 12 *European Law Journal*, 209.

2 N. Walker, 'The Idea of Constitutional Pluralism' (2002) 65 *Modern Law Review*, 317.

3 *Ibid.*, 342.

4 C. Scott, 'Regulating Constitutions', in *Regulating Law*, C. Parker, C. Scott, N. Lacey, and J. Braithwaite (eds) (Oxford, Oxford University Press, 2004), pp. 226-245.

'Impact assessment' in the EU context refers to the commitment by – at first and most notably – the European Commission – later followed by the European Parliament and the Council of Ministers – to perform rigorous ex ante assessment of major (legislative) proposals. The basic thesis defended here is that the impact of IA on the way legislation is made in the EU is potentially so profound that constitutional scholarship ought to take notice, even if its traditional tools and paradigms do not suffice. In investigating the use of impact assessment in EU lawmaking from a constitutional perspective, this thesis aims to contribute to the so far limited body of legal literature that analyses the creation of European legislation beyond the description of the formal characteristics of the legislative process.[5]

I.1 Introducing EU impact assessment

In 2002 the European Commission announced its intention to use impact assessment[6] as a 'general purpose impact analysis tool' in the preparation of proposals, in accordance with recommendations from the Mandelkern group on Better Regulation.[7] A pilot project with 21 proposals took off in 2003 and continued for a second year in 2004 with a slightly increased number of proposals. From 2005 onwards impact assessment came to cover all proposals in the Commission's Legislative and Work Programme (CLWP).[8]

The basic rationale of the European Commission impact assessment procedure is the following:

> Proposals must be prepared on the basis of an effective analysis of whether it is appropriate to intervene at EU level and whether regulatory intervention is needed. If so, the analysis must also assess the potential economic, social and environmental impacts.[9]

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5 D. Wincott, 'Political Theory, Law and European Union', in *New Legal Dynamics*, J. Shaw and G. More (eds) (Oxford, Clarendon Press, 1995), p. 299.

6 Not to be confused with the Community law obligation for Member States to carry out 'environmental impact assessments' on projects or plans. See Council Directive 97/11 amending Directive 85/337 on the assessment of the effects of certain public and private projects on the environment, and Directive 2001/42 of the European Parliament and of the Council on the Assessment of the Effects of Certain Plans and Programmes on the Environment.

7 The Mandelkern Group was composed of Member State experts on better regulation and chaired by Dieudonné Mandelkern, a French government official. It was set up by Ministers of Public Administration, in November 2000 to provide recommendations for a strategy to improve the European regulatory environment. The Mandelkern report was presented to the Laeken European Council in November 2001. Mandelkern Group on Better Regulation, *Final Report* (Brussels, 2001).

8 COM(2005) 97. For all public documents short references have been used in the footnotes. The full references can be found in the Table of Documents, see p. 289.

9 COM(2001) 428 final.

The main issue impact assessment is meant to address is a lack of 'evidence-based decision-making' in EU legislative processes. In doing all of the above IA is meant to function as 'an aid to decision-making, not a substitute for political judgment'.[10] The actual procedure consists of a series of analytical steps to be carried out at the bureaucratic level: problem identification, definition of the objectives, development of the main policy options, impact analysis, comparison of the options in the light of their impact and an outline for policy monitoring and evaluation.[11] Impact assessment should be conducted early on in the policy process, before the proposal is published or even prepared. The existing procedures for pre-legislative consultation and collection of expertise are maintained, but integrated in the IA process as much as possible so that the results can inform the assessment. An IA report[12] is compiled and published together with the proposal, as a means of making transparent the reasoning behind the proposed regulatory intervention as well as the various impacts as estimated by the Commission and the trade-offs between sets of impacts across policy options.

The IA procedure has been taken to the next level of institutionalisation after the adoption of new Impact Assessment Guidelines[13] by the European Commission in June 2005 and the adoption of an Inter-Institutional Common Approach to Impact Assessment by the three Institutions in November 2005. This latter document contains a further elaboration of the pre-existing commitment by the European Parliament and the Council to not only use Commission IAs but also produce their own when they propose 'substantive amendments'.[14] This progressive 'inter-institutionalisation'[15] warrants using the term 'IA regime'[16] rather than just 'IA procedure', as we are dealing with much more than a procedure. Hereafter the abbreviation 'EU IA' will be used to indicate this regime, as part of an effort to stress that impact assessment is more than a bureaucratic tool used for internal Commission purposes only. From being seen as 'somewhat of a Cinderella subject',[17] impact assessment

10 COM(2002) 276 final, 3.
11 SEC(2005) 791.
12 Often simply referred to as the 'impact assessment' even if in fact the term 'impact assessment' covers the whole process and not just the report.
13 SEC(2005) 791.
14 Inter-Institutional Agreement on Better Lawmaking (2003), Article 30.
15 A.C.M. Meuwese, 'Inter-institutionalising EU Impact Assessment', in Better Regulation, S. Weatherill (ed.) (Oxford, Hart Publishing, 2007), pp. 287-309.
16 The following definition of 'regulatory regime' is given by Hood et al.: 'the complex institutional geography, rules, practice and animating ideas associated with regulating particular aspects of social and economic life', C. Hood, H. Rothstein and R. Baldwin, The government of risk: understanding risk regulation regimes (Oxford, Oxford University Press, 2001), p. 9.
17 Graham Mather, 'Q&A session with Günter Verheugen', Edinburgh Conference on Competitiveness and Consultation (Edinburgh, 2005).

now has now taken centre stage in policy debates and received recognition in academic writing.

I.2 Research on impact assessment

Impact assessment as a research subject can be difficult to tackle as it transgresses many traditional areas, for instance by blurring the boundaries between 'legislative politics' and 'executive politics' as separate categories. Research on IA is fragmented and although not necessarily tied to specific disciplines, its focus is often linked to specific 'research communities'. One example is the Europe-wide community of sustainability researchers, some of whom have shifted their research focus from 'sustainability impact assessment' or 'environmental impact assessment' to 'integrated impact assessment'.[18] Conversely there are those 'research communities' that could be expected to take IA to heart as a research topic but who have remained largely silent on the subject. Legislative studies is an example although this is a scattered field, ranging from research on 'legislative drafting' with a juristic streak to studies on parliamentary politics, for instance on voting patterns.

In the United States IA research is much more developed but dominated by economists, who often see it as their task to check on the numbers produced by public bodies and even to engage in macro-level cost-benefit analysis of the totality of the 'regulatory stock'.[19] In Europe neither the numbers nor the tradition are in place to inspire this type of research. Something of an 'IA community' has emerged in the last two years, fuelled by public research money from among others the European Commission, keen to ensure research is relevant for policy-makers. These projects are either of a comparative nature[20] or mainly concerned with gathering data on individual impact assessments at Member State level.[21]

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18 European Environment and Sustainable Development Advisory Councils (EEAC), *Impact Assessment of European Commission Policies: Achievements and Prospects* (Brussels, 2006); J. Hertin, A. Jordan, M. Nilsson, B. Nykvist, D. Russel and J. Turnpenny, 'The practice of policy assessment in Europe: An institutional and political analysis', Matisse Working Paper no 6 (2007); Kirkpatrick and George (2007); Volkery, Hertin and Jacob (forthcoming); D. Wilkinson, M. Fergusson, C. Bowyer, J. Brown, A. Ladefoged, C. Monkhouse and A. Zdanowicz, *Sustainable Development in the European Commission's Integrated Impact Assessments for 2003* (London, 2004).

19 R.W. Hahn, J.K. Burnett, Y.I. Chan, E.A. Mader and P.R. Moyle, 'Assessing the Quality of Regulatory Impact Analyses', AEI-Brooking Joint Center for Regulatory Studies (Washington DC, 2000).

20 'Evaluating Impact Assessment' (EVIA), see http://web.fu-berlin.de/ffu/evia/ (last accessed 15 July 2007).

21 'European Network for Better Regulation' (ENBR), see http://www.enbr.org/ (last accessed 15 July 2007).

As IA becomes more widely known, it is entirely feasible that a strand of research will emerge which is not *about* IA as much as it is *using* IA as sources for policy analysis more generally, as IA reports contain a wealth of information on policy-making by the European Commission which was simply not available before.

I.2.1 Political science research on IA

Much of the existing research on impact assessment in Europe is political science oriented.[22] The phrase 'we need an impact assessment of impact assessments'[23] has become some sort of a punch line at conferences on the subject. Three types of tests for IA regimes have been proposed in the literature: compliance tests (whether IA complies with the procedural requirements as laid down in laws, policies or guidelines), performance tests (measuring the quality of the analysis undertaken) and function tests (evaluating the actual effect of the regulatory tool or institution on the quality of the regulatory outcome).[24] Of these, compliance tests are the easiest to carry out, although performance tests and function tests are more likely to render interesting results. However for the latter – close to the American research tradition – there is no clear-cut methodology and with such limited experience with IA in Europe, there is little incentive to develop one. The main problem with the former is that in order to measure the performance of IA, there needs to be consensus on the goals of EU IA from which benchmarks can then derived. Such consensus does not exist. The disagreement does not only concern the substantive goals of IA, such as 'deregulation', 'achieving the greatest net benefits for society' or 'ensuring the sustainability of policies' but also its function or goal in the policy process.

The literature is dominated by scorecard approaches,[25] aimed at measuring the success of regulatory policy tools, ignoring their governance aspects. Renda

22 An exception is Weatherill, S. (ed.), *Better Regulation* (Oxford, Hart Publishing, 2007) which contains contributions from legal academics and practitioners.

23 Philip Whitehead at the UK Presidency Better Regulation Conference, Edinburgh 22-23 September 2005.

24 C.M. Radaelli, 'How context matters: regulatory quality in the European Union', paper delivered to the PSA Conference (Lincoln, 2004). See also J. Konvitz, 'Improving Regulatory Outcomes: Ex-Post Evaluation', Hearing at the European Parliament on Implementation, Impact and Consequences of Internal Market Legislation (Brussels, 2005). Konvitz and Radaelli mention more or less the same tests, based on Harrington and Morgenstern 2003.

25 Hahn et al. (2000); N. Lee and C. Kirkpatrick, 'A pilot Study on the Quality of European Commission Extended Impact Assessment. Draft for consultation, Impact Assessment Research Centre, Institute for Development Policy and Management, University of Manchester, 21 June 2004 (Manchester, 2004); A. Renda, *Impact Assessment in the EU. The State of the Art and the Art of the State*, Centre for European Policy Studies (Brussels, 2006); F. Vibert, *The EU's New System of Regulatory Impact Assessment – A Scorecard*, European Policy Forum (London, 2004); F. Vibert, *The Itch to Regulate: Confirmation Bias and the European Commission's New System of Impact Assessment*, European Policy Forum (London, 2005).

carried out an evaluation study of the IA practice in the European Commission over the years 2003-2005 using a scorecard based on the Commission's own guidelines, but interpreted in an overly stringent way.[26] The result was that some representatives from the Commission felt it was incorrect to hold Commission IAs to a standard the Commission never set for itself, whereas others felt that the benchmarks used by Renda represented an 'international standard'.[27] Similar contention surround the more qualitatively oriented 'scorecards' by Vibert.[28]

In a research project for DG Enterprise, Radaelli and De Francesco have developed 'indicators of regulatory quality' that can be used to measure the quality of IA systems in various stages of development.[29] These indicators however are explicitly meant to be used in real-life policy-making and that is why it is left to those using them to accord weightings to the indicators and to come up with a way to aggregate the results. A final example of political scientific work on impact assessment is Rowe's article on 'legislative impact assessment' in which he takes the extent to which IA contributes to solving the principal-agent problem as a measure of quality.[30]

I.2.2 Normative research on IA

A further, normative question that returns frequently in the context of IA is whether this kind of thorough, economic ex-ante testing of policies and legislation is desirable. In the United States impact assessment – or 'regulatory impact analysis' as it is often called there – has existed in various forms for a few decades and has had strong advocates as well as opponents all along the way. Some authors believe that the explicit valuation that IA imposes is harmful.[31] Others believe too much emphasis on economic analysis of impacts overemphasizes the instrumentality of legislation,[32] an argument that can be linked with the 'dignity of legislation' forcefully advocated by Waldron.[33] Again others have submitted that when it comes to impact assessment 'the

26 Renda (2006).
27 Discussion at the CEPS conference 'Impact Assessment in the EU, taking stock and looking forwards' on 23 January 2006 in Brussels.
28 Vibert (2004); Vibert (2005).
29 C.M. Radaelli, 'Indicators of Regulatory Quality', report for DG Enterprise, European Commission (Brussels, 2004); C.M. Radaelli and F. De Francesco, *Regulatory Quality in Europe: Concepts, Measures, and Policy Processes* (Manchester, Manchester University Press, 2007).
30 G.C. Rowe, 'Tools for the control of political and administrative agents: impact assessment and administrative governance in the European Union', in *EU Administrative Governance*, H.C. Hofmann and A.H. Türk (eds) (Cheltenham, Edward Elgar, 2006), pp. 448-511.
31 E.g. A. Sen, 'The Discipline of Cost-Benefit Analysis' (2000) 29 *Journal of Legal Studies*, 937 *et seq*.
32 L. Siedentop, *Democracy in Europe* (London, Allen Lane The Penguin Press, 2000).
33 J. Waldron, *The dignity of legislation* (Cambridge, Cambridge University Press, 1999).

theory fundamentally misconstrues the political process'.[34] Here 'theory' presumably refers to public choice theory, which as will be shown in chapter II is by no means the only theory that can be used to justify IA.

I.3 THIS RESEARCH PROJECT

On what basis are legislative decisions made? When confronted with this question a legal scholar is likely to immediately start searching for the relevant competences and legal restraints. A political scientist will typically interpret the question as needing an answer that takes into account institutions, interests, behavioural patterns (depending on their scholarly allegiances) and other factors which empirical research has shown to be relevant in approximating the social reality of decision-making processes. A practitioner will probably give an answer that includes both 'political reality' and 'available evidence'. All these perspectives will play a role in this thesis which is centrally about the relation between impact assessment and the legislative decision it is meant to facilitate. This project starts from the observation that a) the legal perspective is missing from most of the research on IA and b) the research outcome of more evaluative studies is undermined by fundamental disagreement about what kind of 'beast' EU IA really is.

The obvious relevance of IA to law stems from its link with legal principles and requirements in legislative drafting guidelines (e.g. the condition that self-regulation should be explicitly considered as part of the lawmaking process). These norms – although quite far-reaching if taken on face value – tend to be rather meaningless because there is often no procedure through which these requirements are operationalised. Impact assessment is a possible means of implementing such quality standards, as well as principles of good legislation more broadly, making monitoring and enforcement a real possibility. This is not to say that impact assessment in the EU does all this, but given the express ambitions of the EU on this front it is worth an investigation.

The normative concerns summed up above (see I.2.2) can be considered as the stakes behind this research project rather than the direct object of it. This project aims to facilitate ideological discussions by contributing to the preliminary step of uncovering the norms that govern both the procedural and the substantive aspects of the EU legislative process. Therefore – without completely overlooking the powerful theoretical arguments for and against introducing IA – this project will adopt a largely neutral stance on the desirability of IA. A world-wide, partly OECD-driven trend to subject proposed legislation to a consolidated set of mostly economic tests to measure its impacts can be observed. This thesis starts from the assumption that this trend has

34 C. Harlow, *Accountability in the European Union* (Oxford, Oxford University Press, 2002), p. 66.

gained firm footing in the EU. The project focuses on different uses of IA and how these fit with the particularities of EU lawmaking.

I.3.1 Main research question

Regulatory policy, and IA systems in particular, inevitably have an impact on 'who can decide what under which conditions?', the classic basic question of constitutional law. The aim of this thesis is to assess the normative force (or lack thereof) exerted by impact assessments from the standpoint of European constitutional law. The constitutional relevance of IA in general has been noticed here and there, even in a glossy brochure the Finnish Ministry of Trade and Industry prepared to showcase achievements in the field of regulatory reform.

> The impact assessment of regulations has constitutional tasks. Impact assessment provides information that is needed in the evaluation of the proportionality and necessity of the protection of freedom of trade, property, private life and personal data, and the restrictions of financial, social and cultural rights safeguarded by the constitution in order to protect the generally accepted interests in accordance with civil rights or the constitution. Especially the proportionality of various restrictions on obligations and rights imposed on individuals may only be considered on the basis of sufficient impact assessment.[35]

The source may be somewhat conspicuous, the observation is entirely to the point. The constitutional framework sets the outer boundaries for the exercise of public power, including the adoption of regulation. Meta-policies like 'Better Regulation' clarify what citizens can legitimately expect from the way public power is exercised, by spelling out positive principles for regulation as well as defining tools to implement them.[36]

However, no previous research has been done on the detailed dynamics between constitutional law and impact assessment regimes. The main question of this research project is: what is the relationship between the EU impact assessment regime and the EU constitutional framework?

I.3.2 The 'aid not substitute' conundrum

Agreeing on the importance of impact assessment is one thing, agreeing on which role it should play in the legislative process is quite another. As stated above strengthening the evidence-base of lawmaking is the most obvious

35 Finnish Ministry of Trade and Industry, 'SÄVY Business Impact Assessment Project', Report from the year 2006 (Helsinki, 2006), p. 13.

36 Radaelli and De Francesco (2007), p. 5.

institutional goal of IA. However as the showpiece of the 'Better Regulation' programme IA has come to carry the weight of wider problems such as concerns for the competitiveness of European business and the constitutional legitimacy deficit. These overarching issues are supposed to be addressed by IA in a various ways: by improving and simplifying the regulatory environment, ensuring the consistency between Community policies, enhancing communication with the citizen and changing the legislative culture within the European Commission. This ambivalence regarding the goals of IA in the EU context can be traced back to the first Commission Communication on IA, which speaks of using IA to 'guide and justify the choice of the right instrument at the appropriate level of intensity of European action'.[37] The same document goes on to state that IA will also 'provide the legislator with more accurate and better structured information on the positive and negative impacts, having regard to economic, social and environmental aspects'. Lastly, IA will constitute a means of 'selecting, during the work programming phase, those initiatives which are really necessary.'[38]

From all of this one concept emerges: IA as a means of 'informing the EU legislator'. But the tensions inherent in this concept become clear as well. How can impact assessment be expected to tackle all those problems of EU legislation if political judgment can always prevail? The next question is: if we take the stronger language (IA as a means of 'selecting' initiatives) seriously then where is the line between informing and fettering legislative discretion? What is the force of IA for instance if an impact assessment clearly shows one option for a legislative measure to be much more costly than other, but certain actors prefer it because of specific benefits that it has for a specific group in society? And will the institutional balance between the co-legislators be distorted by the introduction of a tool aimed at evidence-based decision-making? If the Commission is not only the 'guardian of the Treaties' but also the 'guardian of reason', will this strengthen or weaken its position vis-à-vis the other Institutions?

All these questions relate back to the 'aid not substitute' conundrum: a status for IA as a decision-making tool would cause institutional problems and possibly even be unconstitutional. But if IA carries hardly any weight, what is the point of investing in such a burdensome procedure? However, there may be a middle way for IA, namely as an information tool. In order to pinpoint where EU IA stands in the conundrum three different roles for IA are analysed in this thesis:

1. *To what extent is EU IA a catalyst of legal principles?*
   This is the most basic level of the analysis; even in the most positivist approaches the relevance of uncovering 'norms which are routinely applied

37 COM(2002) 275 final, pp. 3-4.
38 *Ibid.*

to the exercise of legislative power'[39] and their relationship to legal principles is undisputed. In other words, because of their scope and subject matter IA rules are at least *relevant* to the study of EU constitutional law.

Obviously IA is only one mechanism among many that can play a role in operationalising principles in the daily practice of EU lawmaking (pre-legislative scrutiny by national parliaments, judicial review), not to mention wider political, or psychological factors.[40] However, of all these mechanisms, IA is the one that most explicitly plays a role as a vehicle for various trade-off devices already at work in EU lawmaking such as the proportionality principle and the precautionary principle. The most salient example of a principle that could find a new mode of operationalisation through IA is the subsidiarity principle (Article 5 TEC) which on most interpretations requires some degree of rational consideration of the opportunity of Community action.

2. *To what extent is EU IA a constraint on the legislative process?*
   At this level we assess whether the role of IA goes further than merely operationalising existing principles. Apart from its potential role in operationalising legal principles (see above), IA itself is no legal requirement at the moment. However, perhaps a tool that inspires deference from legislators and regulators does not need a special status in the hierarchy of norms. This thesis aims to investigate whether such deference is developing. Does impact assessment work as a fetter on legislative discretion in any way?
3. *To what extent is EU IA a space for constitutional discourse?*
   It is well known from literature on constitutionalism that '[l]egislators easily and naturally express their ideological differences as conflicts about the nature and content of rights.'[41] According to Stone Sweet, when political parties in Parliament battle to implement their own version of a right, they deliberate the constitutional law and push the development of the constitution in a certain direction. This leads him to conclude that the constitution has the capacity not only to constrain legislative behaviour but also to produce practice.[42] This thesis analyses by analogy whether constitutional differences are also being expressed as conflicts about the assessment of impacts.

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39 Scott (2004).

40 K. Sideri, *Law's Practical Wisdom* (Aldershot, Ashgate Publishing, 2007). Sideri argues that the prevailing 'juridico-administrative rationality' among many officials can mean that the very early thinking already revolves around legal measures and builds on existing legal concepts.

41 J. Waldron, *Law and Disagreement*, (Oxford, Oxford University Press, 1999).

42 A. Stone Sweet, 'Constitutional Politics: The reciprocal impact of lawmaking and constitutional adjudication', in *Lawmaking in the European Union*, P.P. Craig and C. Harlow (eds) (London, Kluwer Law International, 1998), pp. 111-134.

I.3.3 Obstacles

The fact that the Commission is still in the formative stages of developing a European approach to IA, with the other two main actors, the European Parliament and the Council of Ministers only just starting to implement IA in their lawmaking routines, is certainly an obstacle for research on the topic. However, it is possible to map some directions and patterns concerning the role IA is starting to play in the EU legislative process. Besides, it is an express, secondary aim of this thesis to experiment with ways of detecting shifts in norms relevant to lawmaking processes, which may one day become legal norms.

A second obstacle is that traditional legal research methods and frameworks do not suffice to answer the research questions. Assessing processes of constitutionalization is a problematic exercise as available frameworks and criteria tend to be self-referential. For instance, Craig proposes the following preconditions. A rule has to be:

a) enshrined in a norm of constitutional importance and
b) laying down overarching principles,

in order to be eligible for a constitutional status.[43] However, this leads to unsatisfying results, for example the new legal regime of Community administration would qualify as an instance of 'constitutionalization of Community administration'[44] – because of the fact that it has been enshrined in the new Financial Regulation (dubbed a norm of constitutional importance for the occasion) – whereas IA cannot. Given that – as this thesis argues, see III.5.2 – IA has greater stature within the internal Commission hierarchy of norms than ex-ante evaluation (a practice based on that same Financial Regulation), this is a clear sign that these criteria do not allow to depict the constitutional reality.

In a 1997 article Craig has also emphasized the need to have empirical research inform a normative assessment of the European legislative process. In that piece he took proposals for change – Better Regulation *avant la lettre* – as a starting point for asking what we can learn from these proposals more generally about the problems of democracy and legitimacy within the Community.[45] In the same article Craig mentions four related issues as recurring themes in the debate on reform of the EU legislative process: the necessity for the preservation of the institutional balance, the retention of the Commission's sole right of initiative, the need to simplify the existing complex provisions for the making of legislation and the problems flowing from the Union's involvement in the fields of foreign and security policy, and justice and home

43 P.P. Craig, 'The Constitutionalization of Community Administration', Jean Monnet Working Paper, 3/03 (Florence, 2003).

44 *Ibid.*

45 P.P. Craig, 'Democracy and Rule-making Within the EC: An Empirical and Normative Assessment' (1997) 3 *European Law Journal,* 105-130.

affairs. A decade later these items are still on the explicit constitutional agenda. This time around, the new IA procedure offers on opportunity to carry out the type of interdisciplinary research on EU lawmaking Craig was hinting at.

I.3.4 A limited interdisciplinary approach

It is easy to pay lip service to 'interdisciplinary', causing it to be used sometimes as a label for research that is really 'non-disciplinary'.[46] Especially research using a case study approach is sometimes presented as 'interdisciplinary' rather lightly, even if the absence of an explicit theoretical component detaches the work from any discipline, let alone more than one discipline.[47] An important distinction to make is the one between interdisciplinarity and multidisciplinarity. The latter implies an eclectic use of disciplines in answering a research question, the former is more ambitious in the sense that it is aimed at *merging* at least two disciplines. Yet there is a lighter form of interdisciplinarity which uses 'secondary' disciplines to inform the main discipline.

This thesis aims to be interdisciplinary in the latter sense only, with constitutional law remaining the primary discipline. But why bother complementing constitutional law analysis with insights from other disciplines? By sticking to traditional legal research methods such as case law analysis and interpretation of legal texts scholars will often fail to capture developments effectively steering the exercise of public power. If constitutional law scholarship wants to stand a chance of defending itself against growing criticisms raised against it, such as that it is selectively normative, statist and self-contained[48] it needs to look for new sources and approaches.

Where to look? A logical candidate is political science as the two seem well-matched: not only the subject matter (public exercise of authority) but also certain research activities, notably description and classification are common to both disciplines. However, even if a lot of issues in constitutional law are 'political' and a lot of political science literature gladly makes references to constitutional law scholarship, the two disciplines ask fundamentally different questions. Within (mainstream) political science the most highly valued type of research activity is explanation. 'Why and under which conditions does IA emerge or become an influence in the decision-making process?', could be an appropriate starting point for a political science research project on IA. The success of such a research project then entirely depends on the research design, on finding the right variables, acquiring high quality data and interpreting them in a credible way so as to verify or falsify a small part of a large theory.

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46 M. Cini and A.K. Bourne (eds), *European Union Studies* (Basingstoke, Palgrave, 2005), p. 7.

47 R. Hirschl, 'The Question of Case Selection in Comparative Constitutional Law', University of Toronto Legal Studies Series (Toronto, 2006).

48 See Walker (2002), 319 for an overview of these criticisms.

One of the variables can be connected to the legal system, but these studies tend to refrain from looking inside legal systems. Legal studies will usually look *only* inside legal systems, whereas constitutional legal studies tend to ask questions of authority: 'who is allowed to interpret legislation or to make binding decisions?', 'what protection mechanisms for citizens are in place?', 'who is competent to create law under which conditions?' and, perhaps most importantly, 'how does this fit in with the highest norms around, to be found in constitutions and treaties?'. Seen in this light, constitutional scholarship is much closer to legal scholarship than to political science. Indeed constitutional law research that builds on fully fledged political science research design, will probably end up answering political science questions.[49] This project seeks to take a limited interdisciplinary approach, using empirical techniques in as far as is necessary to ensure that the actual effects of meta-rules play a part in the constitutional analysis.[50]

A detour via private law scholarship leads to a surprising option. Private law analysis has been borrowing from regulation studies[51] in its approach to, for instance, self-regulation. It is now hardly controversial to advocate that '*de facto* binding' norms can in some cases be equated to 'legally binding' norms because of the necessity to follow them for inclusion the market. Transposing this presumption to constitutional law by replacing 'the market' with 'the decision-making process' is more controversial, but regulation studies seems the appropriate 'secondary discipline' for this project.

Regulation approaches are traditionally designed for substantive policy areas, not for the meta-level of the regulation of the public sector itself. The dominant strand of regulation scholarship on the other hand is primarily concerned with effective problem solving, thus mainly applying instrumental logic. Although attempts have been made to incorporate instrumental logic into constitutionalist thinking,[52] the majority of constitutional law literature operates from a competence-oriented logic. Until recently '[o]nly a minority of constitutional lawyers and political scientists have recognized regulation

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49 See Hirschl (2006). In this paper a plea for more conscious and structured use of research methods by scholars of comparative constitutional law turns into a plea for them to become comparative political scientists and embrace causal explanation as their highest research goal. For a critique on this paper see http://comparativelawblog.blogspot.com/2006/08/anne-meuweses-comment-on-hirschls.html (last accessed 17 September 2006).

50 The project starts from the basic assumption that 'institutions matter' and that IA as 'socially constituted, historically evolving, and/or interest-based rules of interaction that represent incentives, opportunities, and/or constraints for individual and collective actors' qualifies as an institution. It thus takes a neo-institutionalist approach, but only in the passive sense that it assumes that IA, as an institution, has the capacity to influence the behaviour of decision-making bodies in Europe, without aspiring to make a contribution to neo-institutionalist theory formation.

51 H. Collins, *Regulating Contracts* (Oxford, Oxford University Press, 1999).

52 S.L. Elkin and K.E. Soltan (eds), *A New Constitutionalism. Designing Political Institutions for a Good Society* (Chicago/London, The University of Chicago Press, 1993).

inside government as a key part of accountability regimes'.[53] Now there is a growing literature that studies regulation in its political and constitutional context, namely the 'social structures and institutions that allocate power at the macro-political level'.[54]

Introducing meta-regulation

As part of this emerging tradition the concepts of 'regulation inside government' and 'meta-regulation' are developing. In order to view IA as a meta-regulatory regime one will have to accept first that the 'particular aspects of social and economic life'[55] it is regulating amounts to the activity of lawmaking itself rather than a substantive area of the law. 'We are not accustomed to think of government as "regulating" itself', as the authors of *Regulation inside Government* write whilst asking whether there is such a thing as 'a regulatory state inside the state'.[56] Their answer is a clear 'yes' as they give an account of how 'public organizations are shaped by rules and standards emanating from arm's-length authorities'.[57]

The slightly looser term meta-regulation has recently appeared in the literature to denote the trend that regulatory processes themselves are becoming increasingly regulated. As the term is lacking a distinctive meaning of its own, different authors have used the term to capture related but different phenomena. Roughly the usages fall into two categories: 1) meta-regulation as 'regulation of regulation' and 2) meta-regulation as 'meta-self-regulation'.

An example of the first meaning is Morgan's work which views 'meta-regulation as encompassing any set of institutions and processes that embed regulatory review mechanisms into the every-day routines of governmental policymaking'.[58] Radaelli has proposed to describe Better Regulation as an emerging type of meta-regulation. In his view, Better Regulation policies are essentially meta-regulation because they consist of 'a set of centrally imposed rules that are designed to structure the key stages of the regulatory process (from rule formulation, via RIA, to the simplification of existing rules and the removal of administrative burdens) with the aim of achieving certain improvements in regulatory performance (e.g., targets of burdens reduction, cost-

53 C. Hood, C. Scott, O. James, G. Jones and T. Travers, *Regulation inside Government. Waste-Watchers, Quality Police and Sleaze-Busters* (Oxford, Oxford University Press, 1999), p. 4.
54 B. Morgan and K. Yeung, *An Introduction to Law and Regulation: Text and Materials* (Cambridge, Cambridge University Press, 2007), p. 4.
55 See the definition of a 'regime' from Hood et al., n. 16 of chapter I.
56 Hood et al. (1999), p. 3.
57 *Ibid.*, pp. 3-4.
58 B. Morgan, *Social Citizenship in the Shadow of Competition: The Bureaucratic Politics of Regulatory Justification* (Aldershot, Ashgate, 2003), p. 57.

effective regulation, increased reliance on market-friendly alternatives to regulation, etc.)'.[59]

In the second, more specific and more normative understanding of the concept of meta-regulation it comes closer to concepts such as 'new modes of governance', 'reflexive law', 'responsive regulation' and 'self-regulation' and is perhaps best summarised as 'indirect regulation'. Here the term meta-regulation is used to indicate that existing capacities for control in organizations are steered through meta-regulation rather than the organizations being exposed to norms directly.[60] An example is the work of Scott who speaks of audit institutions as 'meta-regulators' with the capacity to steer the self-regulatory capacities of public sector organizations in respect of financial controls.[61]

The term meta-regulation will be used in the first meaning ('regulation of regulation') here, whilst borrowing some elements from the stricter concept of 'regulation inside government', so that meta-regulation incorporates the complete chain of regulatory activities: standard-setting, monitoring and enforcement. Regulation studies provides a framework for 'measuring' the relevance of IA in the form of the classical regulation triad of standard-setting, monitoring and enforcement. The question arises how far – if at all – IA moves beyond standard-setting and can be said to develop into a complete meta-regulatory regime. The meta-regulatory angle will be used as 'check' on the main perspective which is viewing IA through a constitutional lens.

I.3.5 Outline

Chapter II describes the development of EU Better Regulation and impact assessment from the perspective of the question 'what could it mean to say that EU IA serves as an aid and not a substitute to political judgment in legislative decision-making?'. Five possible answers to this question are provided in the context of the specificities of EU lawmaking, resulting in a typology of models for EU IA. These models serve as a framework of reference when describing the deepening and widening of the IA regime in the rest of the book. The models lend some help in interpreting seemingly self-standing events relating to IA, for instance by shedding light on the preferences of actors on certain constitutional issues when they engage in IA. Along the way the ques-

59 C.M. Radaelli, 'Whither Better Regulation for the Lisbon Agenda?' (2007) 14 *Journal of European Public Policy*, 196.

60 J. Braithwaite, 'Meta Regulation for Access to Justice', General Aspects of Law (GALA) Seminar Series, University of California, (Berkeley, 2003).

61 C. Scott, 'Speaking Softly Without Big Sticks: Meta-Regulation and Public Sector Audit' (2003) 25 *Law & Policy*, 203-220.

tion whether these models clash and whether one of them fits the EU lawmaking procedure better than others will be touched upon.

Chapter III analyses the framework for IA as developed by the European Commission up until now. There is special attention for the debate on an appropriate review mechanism for IA, including the role of the Impact Assessment Board (IAB). Finally, the link between IA and other Better Regulation tools, as well as various 'legislative support tools', such as explanatory memorandums, the precautionary principle and ex-ante assessment, is explored. Chapter IV sets out how the IA regime became 'inter-institutionalised' – institutionalized as a shared procedure between the three Institutions – and provides an overview of the debates and practice surrounding IA in the European Parliament and the Council of Ministers. Chapter V explores the idea that the three 'co-legislators' are not the only relevant actors in IA processes and analyses the role of national institutions, advisory bodies, review institutions, regulatory bodies, private co-actors and third-country actors respectively. Chapters VI and VII are devoted to the case studies (see I.3.6). Chapter VIII contains the conclusion which focuses on the normative potential of the IA rules using the concepts of 'soft constitutional law' and 'meta-regulation', which partly contrast and partly overlap, to sharpen the image.

I.3.6 Research design of the empirical part

The empirical part of the research is attempting to track how IA – when it 'travels' with the proposal through the legislative process as an information tool – has been used. In doing so, the aim is to achieve a balance between presenting an overall picture of the IA practice in the European Commission, the European Parliament and the Council and diving below the surface by engaging in detailed in-depth research.

The two following research methods have been employed:
a. a survey of legislative practice through document analysis;
b. in-depth case studies of four legislative dossiers.

Document analysis

Because previous research on IA practice in the European Commission[62] has generated results that can also be used in this thesis, the primary data

62 Lee and Kirkpatrick (2004); Radaelli and De Francesco (2007); Renda (2006); The Evaluation Partnership, 'Evaluation of the Commission's Impact Assessment System', SG-02/2006 (Brussels, 2007); J. Torriti, 'Regulatory Impact Analysis in the European Union (EU): which national model to be followed?', paper delivered to the SRA 2004 Annual Meeting, (Palm Springs, 2004); Vibert (2004); Vibert (2005).

collection – a survey of IA practice – concentrates on the European Parliament and the Council. Apart from looking for clues on the use or production of concrete impact assessments by Parliament and Council, this also involves an analysis of the use of IA-related discourse in legislative debates (e.g. stating lack of impact assessment as a reason for opposing a proposal).

It is acknowledged that it is difficult, particularly in the case of the Council, to uncover the traces impact assessment may or may not have left upon negotiations. Summary records and minutes of legislative deliberations, reports, notes, legislative opinions and press releases only reveal part of the story on whether and in what way impact assessments have been used in the legislative process. Often the most valuable documents are not publicly accessible – and applying for access is only possible if one knows of their existence – and any relevance of IA to the daily business of the Institutions (e.g. an MEP demanding an impact assessment as a condition for considering amendments proposed by lobby groups) is only put in writing by chance. This incompleteness is mitigated by the fact that informal interviews have been carried out and parts of the formal interviews carried out for the case studies (see below) have been used to back up findings and trends observed on the basis of documents.

Case study selection and methodology

The selection of the case studies has been carried out as follows. After a general survey of the literature and policy documents and some informal interviews, a shortlist was drawn up consisting of twelve codecision dossiers for which there was anecdotal evidence that the IA had been a factor in the inter-institutional discussion on the proposal. This is deliberate selection on the dependent variable. The aim is *not* to establish under which conditions IA becomes a factor in the legislative process or to test some other cross-case causal relationship. The aim is rather to illustrate the variety of uses as classified in the 'models of IA' in section 0 as well as to analyse into great detail the normative weight IA carries (or lacks) in practice. In order to fulfil this research aim information value is more important than representativeness. Thus, a 'diverse' case selection technique fits best, generating a sample that is representative in the sense of reflecting the full variation of the totality of cases.[63] Once the preselected shortlist of cases was established, the legislative dossiers were scored for some variables relevant to the inter-institutional dynamics in general, including policy area, legal instrument, legislative procedure, *de facto* initiator, legislative time line and timing of IA and whether Community competence was contested. It was decided to have a total of four case studies, because less would not give enough variety and more would not be realistic given the number of interviews

63 J. Gerring, *Case Study Research* (Cambridge, Cambridge University Press, 2007), pp. 88-89.

needed (see below). These case studies are essentially illustrations, making contrasting pairs a good way to present them.

The first two cases were selected on the basis of their similarity as for policy area and issues at stake, but differing legal instruments, legislative procedure and timing of IA relative to the state of policy development and legislative drafting. They are:

1. Framework Legislation on Chemical Substances (establishing REACH)
   DG Environment 2003 – SEC(2003) 1171
2. CAFE (Communication on Thematic Strategy on Air Pollution and Directive on 'Ambient Air Quality and Cleaner Air for Europe')
   DG Environment 2005 – SEC(2005) 1133

Both belong to the substantive area of environmental law and policy, where the Community's competences go largely undisputed. One is a targeted regulation (REACH), the other a broad strategy (CAFE). CAFE is the only case in which the codecision procedure does not apply. Although the codecision arrangements are the only ones giving the European Parliament full decision powers, the Parliament also tries to be heard when other procedures apply. That is why – although the central focus of this thesis is on codecision – one non-codecision file was included. CAFE was deemed particularly suitable, because this 'thematic strategy' is meant to pave the way for further legislative initiatives that will have to go through the codecision procedure.

The last two cases are proposals for directives in different substantive areas, but facing similar issues regarding the legitimacy and legal base of Community intervention. They are:

3. Directive laying down rules on nominal quantities for pre-packed products
   DG Enterprise 2004 – SEC(2004) 1298
4. Directive on data retention
   DG Justice, Liberty and Security 2005 – SEC(2005) 1131

An important difference is that one proposal (data retention) was to some extent Parliament driven (as far as the legal instrument was concerned) whereas the other was not. Apart from dossier analysis, the main material for the case studies came from semi-structured interviews with key representatives of the legislative actors. For each case study a Commission official, an MEP (usually the rapporteur) and one national official who took part in the Council working party has been approached for a formal interview.[64] The question-

64 In one case (data retention) two MEPs have been interviewed. In the REACH case, the assistant of a member of the Committee for the Environment has been interviewed instead of the rapporteur, who was impossible to get hold of as legislative activity was at its height at the time. An anonymised list of interviewees can be found in the Annex.

naire was semi-structured and varied for each of the Institutions in order to accommodate the different roles in the legislative process. Questions related to the interviewees' knowledge of the specific impact assessment(s) prepared for the proposal in question, as well as their perception and appreciation of the IA report, process and use. On top of that the interviews were used to retrieve some factual information about the IA process in those particular cases as well as about the general routine of IA in the Institution the interviewees were representing.

II Informing the EU legislator through IA

Regulation in any political system inevitably has to deal with trade-offs across competing values and policy areas as well as with impacts affecting various groups of society. Agreeing on a set of procedures and institutions that enable regulatory trade-offs to be made in a legitimate manner – the essence of regulatory reform – is one of the greatest difficulties in the EU constitutional debate. As Armstrong has usefully summed up: problems, worries and complaints about EU lawmaking fall into three different categories: 1) problems concerning the juristic (drafting) quality, 2) concerns about the economic impact of legislation on competitiveness and 3) doubts as to the underlying constitutional legitimacy.[1] The first category seems to be standing rather on its own and has mostly been addressed separately from the other two through a series of initiatives and policy documents[2] and will not be of direct interest here. The two latter worries, 'economic legitimacy' and 'constitutional legitimacy' are both important targets of the recent EU Better Regulation strategy of which impact assessment is part (see II.1.3).[3] The constitutional framework sets the outer boundaries for the exercise of public power. Policies like Better Regulation clarify what citizens can legitimately expect from the regulatory environment by spelling out positive principles for regulation as well as defining tools to implement these.[4]

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1 K.A. Armstrong, *Regulation, deregulation, re-regulation*, (London, Kogan Page, 2000); A similar disctinction, namely between redactional quality & accessibility, juristic drafting quality & general principles of good lawmaking, efficiency & effectiveness of the legislation can be found in C.W.A. Timmermans, 'How to improve the quality of community legislation: the viewpoint of the European Commission', in *Improving the Quality of Legislation in Europe*, A.E. Kellerman (ed.) (The Hague/Boston/London, Kluwer Law International, 1998), p. 41.

2 Examples are: the Declaration No 39 on the quality of the drafting of Community Legislation which was adopted at the Amsterdam Intergovernmental Conference in 1997 and the Inter-Institutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation which followed (OJ C 73/1, 17 March 1999), as well as the series of seminars on the theme of quality of legislation organized by the Legal Revisers Group in the Commission Legal Service.

3 More or less around the same time as the revision of the Lisbon strategy took place, the original term 'better lawmaking' was abandoned in favour of 'better regulation'. Opinions vary as to whether the difference between these two terms is a) non-existent b) political or c) a matter of the first being the genus and the latter being the species.

4 Radaelli and De Francesco (2007), p. 5.

II.1 Regulatory reform and legitimacy of EU lawmaking

This section fleshes out the details of the dynamics between two sets of norms that are part of the normative environment of the EU legislator: constitutional norms and Better Regulation norms.

II.1.1 A never-ending story?

The European Council of December 1992 in Edinburgh decided that simplifying and improving the regulatory environment was to be one of the priorities of the Community. In the course of the nineties several policies and agenda-setting papers intended to enhance the quality of legislation were enacted. In 1992 the Commission launched the Sutherland report,[5] which contained recommendations concerning improvements and transparency in Community rules, followed in 1995 by a report from the Group of Independent Experts on Legislative and Administrative Simplification (Molitor report)[6] came up with eighteen recommendations on how to simplify Community legislation. This latter report received the qualification 'never-ending story'[7] from the European Parliament hinting that reform fatigue had already kicked in by the mid-nineties. The Netherlands' government, in the run-up to the Dutch Presidency, set up a working party on the quality of EC legislation, resulting in the Koopmans report.[8] Recommendations included a more structure approach to the choice between directives and regulations, the enactment of guidelines for the quality of EC legislation and the establishment of a Community body reviewing the quality of legislation.

One of the best known Commission initiatives in the area of regulatory reform is SLIM which was initiated in March 1996 and evaluated in 2000.[9] A declaration on the quality of legislative drafting was annexed to the Treaty of Amsterdam and in December 1998 an Inter-Institutional Agreement on common guidelines for the quality of drafting of Community legislation[10] was adopted. Finally, the Business Environment Simplification Task Force

5 SEC(92) 2044.
6 COM(1995) 288/2 final.
7 EP Draft Opinion of the Committee on Constitutional Affairs of the European Parliament, 28 November 2002, p. 4.
8 Koopmans Working Party, *The Quality of EC Legislation* (The Hague, 1995).
9 EP Resolution on the communication from the Commission to the Council and the European Parliament on a review of SLIM: Simpler Legislation for the Internal Market (COM(2000) 104).
10 OJ C 73/1, 17 March 1999.

(BEST) projects – which are still ongoing – should be mentioned here.[11] The most important lesson learnt from these attempts was that political backing and the sense of urgency needed for these complicated operations were lacking. Indeed, the limited success of previous legislative quality policies[12] was an important factor in trying to think bigger when developing the Better Regulation programme.

II.1.2 Better Regulation and how it is different

The run up to the adoption of the Better Regulation strategy started at the Lisbon Council in 2000, which awarded the Commission a mandate to propose a strategy for further coordinated action on regulatory reform.[13] Subsequently options were explored by the Commission in the White Paper on Governance in 2001.[14] National input was channelled through the Mandelkern report which was presented to the Laeken European Council in November 2001.[15]

The constitutive moment of the current Better Regulation strategy was the adoption on 5 June 2002 of the Communication on Better Lawmaking.[16] The Action Plan for simplifying and improving the regulatory environment accompanied the general communication.[17] The Action Plan laid down the main lines of the 'comprehensive strategy to promote Better Regulation in the EU, containing action points for the Commission, the other Community institutions (European Parliament and Council) and the Member States'. Key elements include systematic use of impact assessment by the Commission when preparing policy proposals, establishment of minimum standards for external consultations carried out by the Commission and a programme to simplify and update the existing body of European law. At the same time a communication specifically on impact assessment was issued.[18] The emphasis was still on sustainability and the three main features of what was to develop as the Commission approach to impact assessment (IA as an aid not a substitute for political decision making, the integrated approach and the clear link with subsidiarity and proportionality) were already clearly present.

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11 E.g. on the Streamlining and Simplification of Environment-Related Requirements on Companies (http://ec.europa.eu/enterprise/enterprise_policy/best/best_report.htm) and (http://ec.europa.eu/enterprise/environment/index_home/best_project/intro.htm)(last accessed 15 July 2007).

12 See e.g. Opinion of the European Economic and Social Committee on 'Simplification', (2002/C 48/28), OJ C 48/130, 21 February 2002.

13 Council conclusions – Lisbon (2000).

14 COM(2001) 428 final.

15 Mandelkern report (2001).

16 COM(2002) 275 final, pp. 3-4.

17 COM(2002) 278 final.

18 COM(2002) 276.

There are two main reasons to suppose that Better Regulation will – especially in the medium-long term – have more of an impact than earlier attempts to reform EU lawmaking:

- Better Regulation is made a political priority and explicitly linked to the legitimacy of EU lawmaking (see II.1.3).
- The specific conditions of EU lawmaking are taken into account, culminating in the formalisation of the inter-institutional dimension of regulatory reform (see II.1.4).

These two critical factors are explored in the two remaining sub-sections.

II.1.3 Regulatory legitimacy

> Meta-regulation is increasingly presented as not only serving efficiency values, but also enhancing political legitimation, because it represents a set of otherwise silent interests, 'placing a political gloss on the economic perspective'.[19]

As academic literature started to draw attention to the problem of regulatory quality in addition to the problem of quantity,[20] policy discourse started to increasingly refer to Better Regulation and impact assessment in terms of legitimacy. The current European approach is to present IA as a useful tool to help reinforce the link between citizens and the EU, thus enhancing legitimacy. The credibility crisis in the mid-nineties was mostly to do with the executive tasks of the Commission and with internal administration issues. The new millennium saw the crisis aggravated by a perceived mismatch between the highly complex regulatory tasks and the available regulatory instruments, as well as the contested legitimacy of the increasing level of politicization of the Commission.[21]

Input legitimacy vs output legitimacy

The literature distinguishes between two main types of 'legitimacy': the socially sanctioned obligation to obey (Scharpf's empirical conception) and a legal order's worthiness to be recognised (Habermas' normative conception). These two conceptions are interrelated: a widely shared judgment that a decision is legitimate will lead to a socially sanctioned obligation and a legal order will not easily be found worthy of recognition if it is not capable of fostering

19 Morgan (2003), pp. 84-85.

20 Burns (1998); J. Pelkmans, S. Labory and G. Majone, 'Better EU Regulatory Quality: Assessing Current Initiatives and New Proposals', in *Regulatory Reform and Competitiveness in Europe – Volume I, Horizontal Issues*, G. Galli and J. Pelkmans (eds) (Cheltenham, Edward Elgar, 2000), pp. 461-526.

21 G. Majone, 'The Credibility Crisis of Community Regulation' (2000) 38 *Journal of Common Market Studies*, 273-302.

socially sanctioned obligations. Regardless whether one uses the term 'legitimacy' in a normative or a factual sense, a useful distinction is to be made between 'input legitimacy' and 'output legitimacy'. Input legitimacy presupposes that the legitimacy of a decision or a decision making process depends on who gets to influence it. Output legitimacy looks at whether the outcome of the decision making process is good or acceptable.[22] Of course this is no perfect dichotomy. Most mechanisms relying on input legitimacy either implicitly or explicitly suppose that a good procedure will also lead to a good outcome, just like most mechanisms supported by reference to their outcome would acknowledge the importance of having in place an acceptable decision-making procedure.

According to some authors a third kind of legitimacy is needed to make the analytical framework complete: throughput legitimacy.[23] There is some confusion about this concept. According to some authors this kind of legitimacy is purely about 'transparency'; others say that it is concerned with 'how a decision is made'. In this research project it will be assumed that 'throughput legitimacy' is not a third, self-standing type of legitimacy but rather a convenient expression for the grey zone in between input legitimacy and output legitimacy (see figure II.2 for a graphical clarification). The last section of this chapter, which contains a typology of impact assessment, shows that impact assessment can be concerned with both input and output legitimacy.

Economic legitimacy versus constitutional legitimacy

> [B]etter regulation has been recognized as one of the priorities of the Lisbon agenda, but at the cost of losing some of the initial ambitions in terms of inclusiveness and open governance.[24]

Impact assessment can be easily associated with the so-called 'new constitutionalism' which argues that constitutionalism should also be concerned with the question of how institutions should be designed to achieve positive goals, such as economic efficiency.[25] However, IA can also be placed in the context of the traditional preoccupation of constitutionalism with limiting the arbitrary exercise of political power. Phrased differently, we can say that impact assessment can serve both economic legitimacy and constitutional legitimacy and that there might be a trade-off between these two.

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22 Depending on whether one sees legitimacy as absolute or as dependent on the perception of the public/stakeholders.

23 M. Sie Dhian Ho, 'Democratisering van de EU: permanente evenwichtskunst', in *De staat van de democratie. Democratie voorbij de staat*, E.R. Engelen and M. Sie Dhian Ho (eds) (Amsterdam, Amsterdam University Press, 2004), pp. 151-172.

24 N. Burrows, C. Carter, M. Fletcher and D. Scott, 'The Better Regulation Strategy', Sub Rosa discussion paper (Brussels, 2004).

25 Elkin and Soltan (1993).

Economic legitimacy: competitiveness versus sustainable development

From the beginning this regulatory policy initiative has been linked to the Lisbon strategy, and even more strongly so to its revised version, in which the economic aspects have higher priority than the social and environmental aspects.[26]

The most concrete incentive for the Commission to come up with an impact assessment method consisted of the requests made at successive European Council summits: Lisbon, Stockholm, Göteborg and Laeken. The Lisbon Council in March 2000 represents the moment when the Commission effectively received a Council mandate to initiate a new strategy to simplify and improve the EU's regulatory environment.[27] This mandate was a part of the wider 'Lisbon strategy' aimed at turning the EU into the most competitive economy in the world by 2010. In its conclusions the European Council asked the Commission, the Council and the Member States 'to set out by 2001 a strategy for further co-ordinated action to simplify the regulatory environment, including the performance of public administration, at both national and Community level.'[28]

The Commission presented an interim report at the Stockholm European Council on 7 March 2001 on improving and simplifying the regulatory environment,[29] which set out some ideas for a better lawmaking process. In its conclusions this European Council confirmed the leading role of the Commission: "[t]he Commission, in cooperation with all relevant bodies, will present a strategy for regulatory simplification and quality before the end of 2001".[30] At the next summit in Göteborg in June 2001, the EU Strategy for Sustainable Development was adopted. Whereas the Lisbon European Council had emphasized the social and economic pillars of competitiveness and social inclusiveness, this decision adds a third pillar, namely the environment. According to the sustainable development strategy, economic growth, social inclusion and environmental protection must come together in EU policy-making, certainly in the longer run. The European Council speaks of 'sustainability impact assessment' here.[31] When at the Seville Council in 2002 the establishment of a new, comprehensive Commission impact assessment system was sealed, an internal tension was born: would the IA system be capable of serving both competitiveness and sustainability?

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26 Radaelli (2007).
27 Council conclusions – Lisbon (2000).
28 *Ibid*.
29 COM(2001) 130.
30 Council conclusions – Stockholm (2001).
31 Council conclusions – Göteborg (2001). The conclusions state that "the Commission will include in its action plan for better regulation to be presented to the Laeken European Council mechanisms to ensure that all major policy proposals include a sustainability impact assessment covering their potential economic, social and environmental consequences".

Apart from the image of the EU as a machine producing an ever growing body of unnecessary rules, the development of Better Regulation policy was shaped by the conclusion from the Kok report around the end of 2004 that the EU was failing to deliver on the Lisbon agenda.[32] This led to an attempt by the Barroso Commission to relaunch and reinvigorate the strategy. Its first document on IA, 'Impact Assessment: Next Steps – In support of competitiveness and sustainable development',[33] was explicitly presented as the outcome of a stock-taking exercise. The Next Steps document was followed by the Communication on Better Regulation for Growth and Jobs which was published in March 2005 to set out the Better Regulation agenda of the newly formed Barroso Commission. Unsurprising given the political priorities of the new Commission, Better Regulation was placed clearly in the context of the relaunch of the Lisbon Agenda.

Once competitiveness was established as the one overriding political priority, this put a heavy strain on the IA procedure. Can the aim of an objective counterbalance to political partiality be reconciled with the aim of putting IA to the service of competitiveness?

Constitutional legitimacy I: proportionality and subsidiarity

> The Commission's work will be tested against the requirements of subsidiarity and proportionality: the EU should only act when necessary and in the lightest form consistent with achieving its objectives. The Commission will pay particular attention to ensuring full respect for subsidiarity and proportionality.[34]

Compliance with the principles of subsidiarity and proportionality[35] is 'intimately linked as the measures introduced to improve regulation should make for better compliance with the principles of subsidiarity and proportionality, and vice versa.'[36] Subsidiarity especially is at the core of all efforts to improve regulatory quality in Europe. Ever since the Edinburgh Council Conclusions in 1992 the Commission has reported annually on the application of the principles of subsidiarity and proportionality to the European Council and

32 'Facing the Challenge. The Lisbon strategy for growth and employment', report from the High Level Group chaired by Wim Kok (Luxembourg, 2004).

33 COM(2004) 1377.

34 COM(2005) 531 final, p. 10.

35 The full text of Article 5 TEC is: "The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein. In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community. Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty."

36 Mandelkern report (2001).

the European Parliament.[37] Since 1995 these reports have also taken into account measures taken in the field of better lawmaking and were renamed 'Better Lawmaking reports'. This obligation was formalised in Article 9 of the Protocol on the application of the principles of subsidiarity and proportionality which the Treaty of Amsterdam added to the EC Treaty in 1997. The Protocol also contains a provision which stipulates that the Commission will 'take duly into account the need for any burden, whether financial or administrative, falling upon the Community, national governments, local authorities, economic operators and citizens, to be minimised and proportionate to the objective to be achieved'. Thus proportionality and subsidiarity can be said to provide a constitutional basis for the IA procedure.

Simply put, subsidiarity guides the 'where dimension' of potential European legislative proposals and proportionality addresses the 'how dimension' of the kind of legislative solution once the decision to intervene has been taken.[38] Subsidiarity as a principle of European law has a built-in preference for regulation on the Member State level. This is expressed by the requirement that, in the case of joint competences, the Community should only take action if it can demonstrate it can do *better*. Strictly speaking we are dealing with a test in three parts: 1) there are transnational aspects which cannot be satisfactorily regulated by national measures (necessity test I), 2) national measures alone or lack of Community action would conflict with the requirements of the Treaty establishing the European Community (TEC) or would otherwise significantly damage Member States' interests (necessity test II) and 3) action at Community level would provide clear benefits compared to national measures (added value test). Some would say embedding subsidiarity in economic analysis is a good idea,[39] others contend that the 'blending together of subsidiarity and the more process-oriented issue of legislative quality further dilutes any residual prominence subsidiarity might have had'.[40] It all depends on the type of subsidiarity one adheres to: economic subsidiarity, legal subsidiarity, political subsidiarity, procedural subsidiarity, all of which could potentially be accommodated in a regulatory policy.

The term 'proportionality' is used in (at least) two senses in the context of EU lawmaking. First of all there is 'proportionality *stricto sensu*' which stipulates that the costs of action not be excessive in relation to the benefits of action. Secondly, 'proportionality' in a wider and more commonly used

37 COM(1998) 815; COM(1999) 562; EP Resolution on Commission reports on better lawmaking 1998-1999 (2000).

38 D. Lazer and V. Mayer-Schoenberger, 'Blueprint for Change: Devolution and Subsidiarity in the United States and the European Union', in *The Federal Vision: Legitimacy and Levels of Governance in the United States and the European Union*, K. Nicolaidis and R. Howse (eds) (Oxford, Oxford Univerisity Press, 1999), pp. 118-143.

39 G. de Búrca, 'Reappraising Subsidiarity's Significance after Amsterdam', Harvard Jean Monnet Working Paper, 7/99 (Cambridge MA, 1999).

40 Lazer and Mayer-Schoenberger (1999), p. 137.

sense incorporates three tests: 1) proportionality *stricto sensu*, 2) a least trade restrictive alternative test, and 3) a simple means-ends rationality test.[41]

Constitutional legitimacy II: governance

Years before the enactment of the Better Regulation programme Majone in his influential book *Regulating Europe* has drawn attention to the 'importance and interplay of independence, accountability and legitimacy in any balanced future development of regulatory reform in Europe'.[42] Armstrong has appropriately called attempts at regulatory reform 'a set of lenses through which different sorts of anxieties about the quality of EU governance were refracted'.[43] This seems to ring true for the Better Regulation initiative as well.

The most obvious recent attempts to deal with problems of constitutional legitimacy are linked to the draft Treaty establishing a Constitution for Europe,[44] which has been given a lot of attention in academic writing.[45] But after its failure to materialise sights are set again on the paths of change initiated by the White Paper on Governance[46] in 2001. The impact assessment procedure – as will be shown in this thesis – has become the most tangible change to the EU lawmaking procedures that came out of the Governance project.[47] This 'shadow constitutional project' aimed among other things at addressing problematic issues of legitimacy *within* the existing framework of the Treaties.

The White Paper on Governance can be seen as a response to the Second Report of the Committee of Independent Experts which investigated alleged mismanagement, irregularities and fraud within the Commission on behalf of the European Parliament and came up with proposal for how to tackle these problems.[48] Although the White Paper steers clear from addressing major constitutional issues directly, it does address issues of constitutional significance, such as the implementation powers of the Commission (should be widened) and the Community method (should be maintained). The relevance of the directions chosen in the White Paper for the development of IA will be discussed in section III.1.2.

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41 N. Emiliou, *The Principle of Proportionality in European Law: A Comparative Study* (London, Kluwer Law International, 1996).
42 G. Majone, *Regulating Europe* (London, Routledge, 1996), p. 5.
43 Armstrong (2000), p. 5.
44 OJ 2004 C 310, 25 June 2004.
45 E.g. A. Kinneging (ed.), *Rethinking Europe's Constitution* (Nijmegen, Wolf Legal Publishers, 2007).
46 COM(2001) 428 final of 25 July 2001.
47 SEC(2004) 1377, p. 3.
48 Committee of Independent Experts, 'Second Report on Reform of the Commission. Analysis of current practice and proposals for tackling mismanagement, irregularities and fraud' (Brussels, 1999).

II.1.4 Conditions of EU lawmaking

What has been said about new forms of governance in general[49] is also true for the topic of this thesis: the design of IA cannot simply follow function. All sorts of constraints have to be taken into account, ranging from the constitutional framework to the more banal features of EU lawmaking that can work as enabling and as limiting factors for the institutional design and functioning of IA in the EU context. Compared to national systems regulatory authority at EU level is particularly scattered, layered and fragile. Lawmaking at the EU level is more constrained in at least three important respects: competence, content and procedure.[50] Furthermore, checks and balances in the EU legislative process are somewhat of an oddity from the point of view of comparative public law.[51] The complex structure of the institutional balance between the three Institutions involved in lawmaking culminates in the peculiar role of the Commission. As an independent 'Guardian of the Treaties' it has the sole right of initiative in order to counterbalance the risks majority voting in the European Parliament and Council poses for the smaller countries.[52] In most legislative institutional settings there is a certain coherence between the policy preferences of the parliament and that of the government; this is not necessarily the case at the EU level. Any attempt to improve EU legislative procedures and outcomes is inevitably triggered but also constrained by these circumstances. As this section shows, this is even more strongly the case for impact assessment, aimed at 'informing the legislator' (see I.3.2).

The 'EU legislator'

Who is the legislator in the EU context? The answer to this question depends on the area that is being regulated and the instrument and procedure that the Treaty prescribes accordingly. Even if many Commission documents refer to 'the legislator' or the 'legislative authority' so as to exclude itself,[53] the role of the Commission is so central that it is fair to identify, in the context of the codecision procedure, three main 'co-legislators': the European Commission,

49 A.-M. Slaughter, *A New World Order* (Princeton/Oxford, Princeton University Press, 2004), p. 43.

50 A. Verhoeven, 'Legisprudence and European Law: in Search of the Principles of European Legislation', in *Legisprudence : a new theoretical approach to legislation : proceedings of the fourth Benelux-Scandinavian Symposium on legal theory*, L.J. Wintgens (ed.), The European Academy of Legal Theory series (Oxford, Hart Publishing, 2002), p. 112.

51 W.J.M. Voermans, 'The Coming of Age of the European Legislator', in *Rethinking Europe's Constitution*, A. Kinneging (ed.) (Nijmegen, Wolf Legal Publishers, 2007), pp. 175-196.

52 J. Temple Lang, 'Checks and Balances in the European Union: The Institutional Structure and the 'Community Method'' (2006) 12 *European Public Law*, 127-154.

53 Sometimes even with a capital 'L', see e.g. COM(2005) 462, final.

the European Parliament and the Council. The concept of a legislative act in EC law also differs from that in Member States.[54] The idea of the legislator as the sovereign body with a blank mandate is obsolete, certainly in the European Union. Not only is the mandate often conceived to be construed in a flawed manner because of the weak democratic legitimation of the legislature, any mandate that is left is by no means blank. First of all there is the Treaty, conferring limited powers on the Community. We are dealing with a purposive union rather than with a nation-state that is an end in and of itself. Not only traditionally powerful stakeholders like lobby groups but also citizens are less willing than ever to accept new legislation simply because it is the law. Both groups are looking to 'Brussels' with expectations that the EU will make an effort to 'market' its 'legislative products'. Expressions like 'red-tape' have become part of the vocabulary of many Europeans and stories about overly detailed EU regulation fill the newspapers on a daily basis. Legislation coming from the EU has to be shown to be good these days.[55]

Community method

By the standards of almost every conception the legitimacy of EC legislation (see II.2 on various models of EU lawmaking) is intimately linked to the Community method and to the institutional balance that makes this method possible.[56] The Community method is the very unique combination of legislating by one institution with the exclusive right of initiative (Commission) and two institutions possessing the right to amend the proposals (Council and Parliament). However, many of the problems of legislative quality also arise from the same method, to be exact from the fact that legislative texts have to be negotiated between the three legislative Institutions. To quote the Commission:

> Ideally, agreements on new legislation should not be achieved at the cost of unduly complex solutions that lower the legislative quality.[57]

Thus, consistency with the Community method is the first challenge for EU IA.

The Commission presented a political communication for the purpose of consulting the Council, the European Parliament and the Member States on the main issues of the developing Better Regulation strategy to the Laeken

54 A.H. Türk, *The Concept of Legislation in European Community Law: A Comparative Perspective* (The Hague, Kluwer Law International, 2006).

55 L. Verhey, 'Good governance: towards a European ius commune', in *Towards a European Ius Commune in Legal Education and Research*, M. Faure, J. Smits, and H. Schneider (eds) (Antwerpen/Groningen, Intersentia, 2002), pp. 73-95.

56 W.J.M. Voermans and H.M. Griffioen, 'The European Constitution and the Relation between European and Member State Powers' [2007] *Zeitschrift für Staats- und Europawissenschaften – Journal for Comparative Government and European Policy*, 25-45.

57 Inter-Institutional Agreement on Better Lawmaking (2003), Article 28.

European Council in December 2001.[58] Initially the presentation of a fully-fledged action plan was already foreseen for this meeting, but the European Parliament asked the Commission not to finalise the Action Plan until the consultation period for the White Paper on Governance would end (March 2002), because the choices that were to be made also touched upon the prerogatives of the Parliament.[59] At the European Parliament's plenary meeting on 2 October 2001, the then Commission President Prodi made the commitment not to adopt new proposals on the topic of Better Regulation without first obtaining the opinion of the European Parliament as co-legislator.[60] He also proposed to establish an inter-institutional working group on European governance and Better Regulation.

The European Parliament Resolution on the Commission's White Paper on European Governance, which was adopted in November 2001, is often called 'Kaufmann report' after its rapporteur MEP Sylvia-Yvonne Kaufmann. The rather sharp tone in the following passage from this report shows the strong condemnation by the Parliament of the Commission's way of proceeding so far:

> [The European Parliament] considers that the drafting of an 'action plan for better regulation' by a Council working party (Mandelkern group on Better Regulation) and, at the same time, by a Commission working party with a similar brief, represents a serious breach of the Community method, for Parliament, as co-legislator, was neither informed of, nor involved in, the work of these working parties.[61]

Against this background it is clear that the political communication adopted in December 2001[62] as a means of initiating an inter-institutional debate on Better Regulation in order to respect the Community institutions' prerogatives, was meant most of all to appease the Parliament. This communication mentions the intention to introduce a new IA procedure but sticks to the Göteborg terminology of 'sustainability impact assessment':

> [T]he Commission intends to establish, by the end of 2002, a coherent method for impact analysis to ensure that all major proposals contain, in a form which is proportional and adapted to their content, a sustainability impact assessment covering their economic, social and environmental consequences. The system will be based on an evaluation of the costs and benefits, stressing the economic, social

58 COM(2001) 726.
59 The written version of this request is laid down in the Kaufmann report on the White paper (adopted by the European Parliament on November 28) which contains some firm wording. EP Kaufmann report (2001), 31.
60 *Ibid.*, para. 32.
61 *Ibid.*, p. 13 para. 30.
62 COM(2001) 726.

> and environmental impacts. The impact assessment will define the problem which needs to be addressed, and will analyse the available options, their respective impact, and how the policy will be implemented.[63]

Even from this rough overview of the institutional history of the better lawmaking project, a difference in focus and perspective between the co-legislators in the run-up to the adoption of the Better Regulation action plan emerges. Whereas the Council has focussed on the content and particularly the policy goals to be reached through Better Regulation, the European Parliament has been preoccupied with preserving its own legislative powers, thus paying most attention to the institutional design of the Better Regulation strategy.

The multi-level aspect

> In the context of an EU legislative policy, the question is not how many rules we need, but how much uniformity is required in order to make the EU's legal system function properly.[64]

Typically the economic, political and administrative costs of EU regulation are borne not at the central EU level, but at the national, or sub-national level. Also many of these costs concern both the private and the public sector.[65] Not only the costs, also the processes of lawmaking are dispersed, especially if one interprets the concept of 'legislative actors' in the widest possible sense (so Member States and interest groups included). The multi-level structure is further complicated by the double layer of interests, meaning that actors may have different agendas nationally and supranationally. This poses a further challenge for the design of a regulatory policy and an impact assessment system.

In November 2000, under the French Presidency, the ministers of public affairs established a high level group, chaired by Dieudonné Mandelkern and mandated it to prepare a report on Better Regulation topics. Within this group, which was composed of 15 members and a representative of the Commission, 'rapporteurs' worked on specific issues. Instead of addressing the role of national procedures in improving the overall quality of the EU regulatory environment as was originally envisaged, the Mandelkern report, which was presented to the Internal Market Council on 26 November 2001, focussed on

63 *Ibid.*, 6.

64 E.M.H. Hirsch Ballin and L.A.J. Senden, *Co-actorship in the Development of European Law-making* (The Hague, T.M.C. Asser Press, 2005), p. 7.

65 European Policy Centre, 'Minutes of the Conference 'Better regulation: the EU and the transatlantic dialogue' (Brussels, 2005), p. 15.

the Community institutions, in particular the Commission. The OECD Better Regulation criteria[66] played a prominent role in the analysis.[67]

The Commission felt that some of the recommendations in the Mandelkern report in the implementation phase would need more attentive consideration of the specific features of the Community decision-making process and of the specific powers of each institution. For instance, the practice that sometimes a regulatory instrument is only adopted 'on the express condition that a new instrument be proposed to cover other aspects'.[68] Also, the Commission considered that 'the responsibility of the Member States [was] not sufficiently emphasized'.[69]

Four consecutive EU Presidencies (Ireland, Netherlands, Luxembourg and the UK) issued a joint statement on 26 January 2001, proposing among other things that Council should be consulted on which proposals should undergo impact assessment and that Commission impact assessments should undergo a more formal quality control before adoption of the proposal. The document had a pro-business and efficiency-oriented flavour since it asked the Commission to consider the development of a common method to assess competitiveness impacts and administrative burdens on businesses. An informal steering group was established to oversee the follow-up to this 'Four Presidencies Initiative' as it was called. On 7 December 2004 the initiative was extended to two more Presidencies (Austria and Finland) and subsequently came to be known as the 'Six Presidencies Initiative'.[70]

Contested objectives and competences

> As the single market programme involves reconciling different national regulatory approaches, each of which embodies complex compromises and reflects national

66 They are – in an updated version – 1) adopt at the political level broad programmes of regulatory reform that establish clear objectives and frameworks for implementation, 2) assess impacts and review regulations systematically to ensure that they meet their intended objectives efficiently and effectively in a changing and complex economic and social environment, 3) ensure that regulations, regulatory institutions charged with implementation, and regulatory processes are transparent and non-discriminatory, 4) review and strengthen where necessary the scope, effectiveness and enforcement of competition policy, 5) design economic regulations in all sectors to stimulate competition and efficiency, and eliminate them except where clear evidence demonstrates that they are the best way to serve broad public interests, 6) eliminate unnecessary regulatory barriers to trade and investment through continued liberalisation and enhance the consideration and better integration of market openness throughout the regulatory process, thus strengthening economic efficiency and competitiveness and 7) identify important linkages with other policy objectives and develop policies to achieve those objectives in ways that support reform. See OECD (2005).

67 COM(2002) 275 final; COM(2002) 278 final.

68 COM(2001) 726, p. 3 and footnote 3.

69 *Ibid.*, p. 3.

70 COM(2002) 275 final, p. 3.

> attitudes and preferences, there is contestation about the objectives of regulation, not just its means.[71]

No amount of impact assessment can produce good regulation if there is disagreement about the regulatory objectives. Quite possibly, impact assessment can make things worse by couching the debate in technical language, thus making it easier for the actors involved to gloss over this disagreement.[72] Is there agreement within the EU about the objectives of regulation? A fresh-minded reader who turns to the Treaty for the answer to this question would probably get the impression that this is the case. The text of the Treaty makes it very clear that only certain objectives justify legislative intervention at the European level. The reality is different however.

A large part of EC legislation has been introduced to correct market failures and ensure a level playing field within the internal market. From this some draw the conclusion that therefore *Better* Regulation must be inextricably linked to achieving the optimal equilibrium in regulating the internal market or even a means of returning to the 'core task of stripping down barriers to create a solid internal market'?[73] Before the adoption of EU IA, Radaelli has argued that there is an increasing politicization of EU regulation and that this has created problems of legitimacy of EU regulatory choices.[74] In the meantime single market issues have only become more politicized and this could be a big challenge for IA.[75]

First of all many objectives not strictly supported by the EC Treaty can be brought under the guise of obstacles to the internal market. Secondly, because of the particular institutional setting of the EU with an independent Commission and a highly politicized Parliament, coherence between the objectives of the initiator of legislation on the one hand and the Parliament on the other is lacking. Also within the Commission there is not always agreement. In this context a publication by the European Policy Forum suggests that those

> who are regulated can never be sure that EU regulatory programmes have come to an end. Within the Commission, the Internal Market directorate may think it has brought down transactions costs and is turning from new initiatives to implementation but the Social Affairs or Consumer Affairs directorates may think that

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71 A.R. Young, 'The Politics of Regulation and the Internal Market', in *Handbook of European Union Politics*, K.E. Jorgensen, M.A. Pollack, and B. Rosamond (eds) (London, Sage, 2006), p. 376.

72 D. Helm, 'Regulatory reform, capture, and the regulatory burden' (2006) 22 *Oxford Review of Economic Policy*, 183.

73 Krubasik in European Voice, 'MEPs attack Commission over law-screening 'lapses' ' (Brussels, 2005).

74 C.M. Radaelli, 'Democratising Expertise?', paper delivered to the conference 'la représentation dans l'Union européenne' CERI – Sciences Po Paris, 4 May 2001 (Paris, 2001).

75 Claudio Radaelli at CEPS conference 'Impact Assessment in the EU, taking stock and looking forwards' on 23 January 2006 in Brussels.

> they are only just beginning to tackle the social or consumer protection aspects of financial markets.[76]

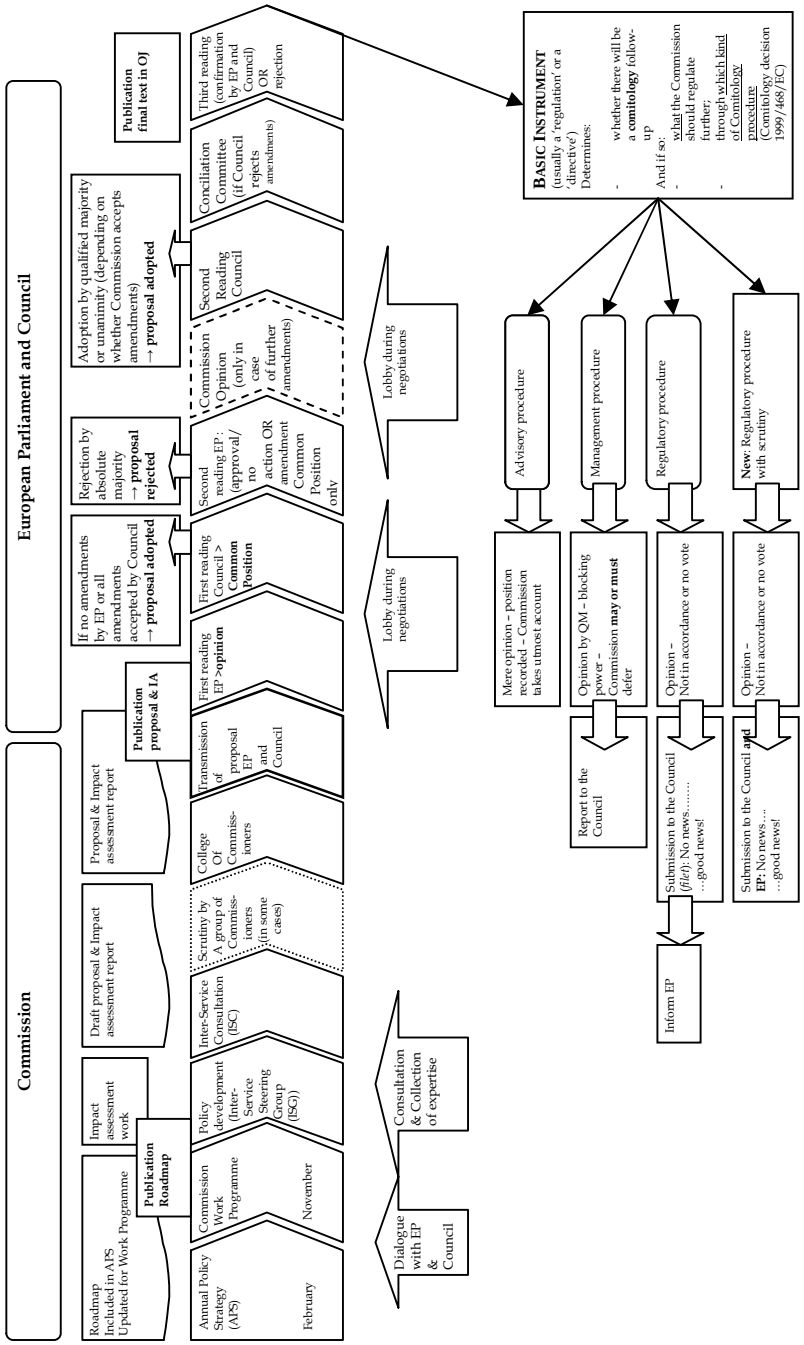
IA inevitably operates in the shadow of competence. The logic of economic analysis is a consequentialist one. The logic of competence can perhaps best be described as 'autopoietically legal':[77] a body has a certain competence or it does not, there is no room for beneficial effects in the equation. Competence tends to be about delimitation of power for the sake of it. However, in certain instances, the determination of competence in the EC context can rely on economic analysis, because it is tied to the centrality of the internal market. A comprehensive impact assessment that takes into account economic, social and environmental impacts could potentially play a facilitating role, moving away the justification of a Commission proposal from a narrow focus on finding a legal basis in the Treaties by offering, thus strengthening the link between competence and evidence.[78]

76 Sideri (2007), p. 103.

77 G. Teubner, 'After Legal Instrumentalism? Strategic Models of Post-regulatory Law' (1984) 12 *International Journal of the Sociology of Law*, 375-400.

78 G. de Búrca, 'Rethinking law in neofunctionalist theory' (2005) 12 *Journal of European Public Policy*, 310–326.

Figure II.1: Flowchart of the codecision procedure and comitology procedure



II.2 Models of EU lawmaking

Majone has observed that normative discourse on regulatory legitimacy tends to focus on 'the same evaluative criteria: expertise, proceduralization, subsidiarity'.[79] This observation has two implications for this research project. First of all, the best way to tackle the concept of legitimacy – not exactly a measurable concept – is to break it down into constitutional values. It is possible to group preferences for certain constitutional values, some of which are explicitly associated with 'good governance' into models of EU lawmaking as Verhoeven has done before.[80] The second implication is that a useful way of applying these models is to place them as 'grids' on normative discourse on Better Regulation. Section II.1.3 has explored how Better Regulation is connected to different types of legitimacy at the very general level; in order to understand specific elements of Better Regulation discourse and practice in terms of legitimacy we need the interface of the models of lawmaking set out in this section.

Values are qualities that render something desirable or valuable in the eyes of a large group of people. Models serve to explain, but mostly to justify, certain institutional settings by reference to certain values. There is a rough consensus as to which values matter in legislative decision-making. Also, most people would agree that there is not one particular model of lawmaking that is always best. What matters is applying the suitable model to the right sets of decisions, to have an appropriate institutional structure in place that will minimize the risks associated with the chosen model. However, people tend to disagree which model is generally the best one and they also disagree which values are generally more important. This disagreement will to some extent be suppressed or managed, for instance by careful decision-making at the constitutional level of a societal entity, by compromising between models, by combining elements from them whenever possible or by steering the entity towards the model which best fits the non-legal preconditions. In the case of the EU however disagreement has largely persisted.

The models proposed below each represent a different configuration of values lending legitimacy to EU lawmaking. None of these models should be taken to perfectly describe either the reality of legislative decision-making at the EU level or the actual positions of participants in the constitutional debate. Neither should we expect that any of these models spells out specific provisions for an EU constitution. Nor are there any fixed institutional structures which come with the models. However when faced with concrete institutional choices, the models usually point towards a certain direction. Also, they help

79 G. Majone, 'Regulatory Legitimacy in the United States and the European Union', in *The Federal Vision. Legitimacy and Levels of Governance in the United States and the European Union*, R. Howse and K. Nicolaidis (eds) (Oxford, Oxford University Press, 2001), pp. 252-275.

80 Verhoeven (2002).

trace inconsistencies between different elements of procedures, institutional regimes or even a constitution. Whenever such an inconsistency occurs, it does not necessarily follow that it needs to be changed. After all, the disagreement the models channel and express is fundamental. And the deeper question of whether constitutions and institutions can or should be build on one model, or whether they should be eclectic, consisting of a mixture of elements from different models, thus trying to mediate between them, goes far beyond the scope of this book. Besides, it is entirely plausible that different types of regulation trigger different models.[81] This is an interesting hypothesis but not one that is explicitly explored in this thesis.

II.2.1 Intergovernmental lawmaking

Although few will dare to claim that European lawmaking *is* intergovernmental, there is a possible argument to be made the intergovernmental features of the EU as a political system are still defining, along the lines of Moravcsik's liberal intergovernmentalism.[82] In this model, the preference formation is predominantly domestic and of an economic nature, with inter-state bargaining and supranational decision-making only occurring if they reduce transaction costs. Consequently, the Council is legitimately the most influential legislative actor and any attempts to 'inform the legislator' would have to take this into account. One way in which this could be done is having a special focus on the effects of proposals for Member States in impact assessments. This model also puts a high value on providing the Ministers in Council with options, although these should not be too far apart in order to make sure they can be combined as part of consensus-building. Subsidiarity is a key value, as is the role of IA in making sure that the Commission stays within the boundaries of its legislative mandate.

II.2.2 Parliamentary lawmaking

For years the parliamentary model has been the most influential one especially as an ideal for legislative decision-making at the EU level. Lately more and more commentators have moved away from this model, arguing that – since the EU is not a nation and the European Parliament cannot be put on a par with a national assembly – the sovereignty-centred thinking which is at the heart of this model may not be appropriate. At the same time this is where

81 A.J. Harcourt and C.M. Radaelli, 'The limits to EU technocratic regulation' (1999) 35 *European Journal of Political Research*, 116.

82 A. Moravcsik, 'Preferences and power in the European Community: A liberal intergovernmentalist approach' (1993) 31 *Journal of Common Market Studies*, 447-472.

the appeal of this model lies for those who would like to see the EU become an entity much like a nation state. If one argues that negative integration (the removal of obstacles) must be followed by positive integration (active harmonisation) then it is only a small step to assuming that this must occur through traditional democracy. In one possible constellation the Commission would act as a kind of federal government, with a bicameral parliament, consisting of a geared up version of the European Parliament and a watered down version of the current Council of Ministers as second chamber. Within this setting, 'the Parliament may even have to act as an arbitrator and intermediary between Community and national interests, using its budgetary, supervisory and censuring powers in a drive for openness, accountability and responsibility against not only the Commission but also the Council'.[83]

II.2.3 Regulatory lawmaking

This model more or less coincides with Majone's famous plea for viewing the EU not as a nation state but as a regulatory state, a *Zweckverband*.[84] If traditional democratic legitimation is considered to be out of the question since no transferral of sovereignty to EU institutions has taken place, this model enters the picture. The goals of the Treaty as well as a reasoned and procedurally fair exercise of the powers associated with those goals are what legitimizes lawmaking at the EU level. The Institutions, and in particular the Commission, can be seen as agencies that have been delegated certain well-delineated competences, the exercise of which is dependent on expertise rather than on resources for redistribution.[85] This delegation of regulatory competences is politically rational: not having to live with the electoral cycle, the Commission is able to take decisions that national governments simply cannot afford even if they see their merits.[86] The integration of markets is the primary goal and the main method to achieve it is to establish a 'level playing field'. The fact that gradually competences have expanded to the regulation of areas like the environment, health and consumer protection can easily be incorporated in this model. The ideal development according to the regulatory model would look something like this: the Commission acts as a dynamic technocracy (for instance through strengthened comitology), with the Council as the body required to ratify Commission action.

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83 Committee of Independent Experts, 'Second Report on Reform of the Commission. Analysis of current practice and proposals for tackling mismanagement, irregularities and fraud' (Brussels, 1999).

84 Majone (1996).

85 Harcourt and Radaelli (1999), 109.

86 Majone (1996), p. 129.

As Harcourt and Radaelli have pointed out, regulatory lawmaking[87] should not be equated with technocratic lawmaking.[88] Technocratic input is not what defines regulatory lawmaking; there are many examples of areas of regulatory law such as media law in which the EU has not managed to avoid politicization.

II.2.4 Bureaucratic lawmaking

> [T]he structure of the EU, as a partial polity, muffles political issues in technical language.[89]

The connotations of 'bureaucratic lawmaking' are often not too positive as this quotation demonstrates. The reasoning in this model asserts that if it is possible to create a system in which evidence-based decision-making is combined with benchmarking the consequences of these decision so as to create a learning cycle, there should be no problem in leaving lawmaking to bureaucrats. The main difference with the regulatory model is that the latter puts much greater emphasis on procedural fairness especially accountability through (political or judicial) review, whereas bureaucratic lawmaking relies more on output legitimacy.[90] This bureaucratic model as well as the one based on judicial review (see II.2.7) are the least relevant, since they are the least likely to have proponents as full models of lawmaking. They are mentioned for the sake of conceptual completeness and because they are helpful in lending perspective to certain arguments in the IA debate.

II.2.5 Participatory lawmaking

This model looks towards more direct forms of democracy in its search for legitimacy. It starts from the pluralistic ideal that allowing everyone considered a stakeholder (lobby groups and citizens) to participate in the lawmaking

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87 Or 'policy-making' in the jargon of political scientists and for the purposes of this section a synonym of 'lawmaking'.

88 Harcourt and Radaelli (1999). This article points out that certain areas cannot escape politicisation even after they have been captured by the regulatory state. It does not "advocate depoliticization and technocratization", as is suggested in D. Levi-Faur, 'Regulatory Governance', in *Europeanization. New Research Agendas*, P. Graziano and M.P. Vink (eds) (Houndmills, Palgrave Macmillan, 2007), p. 111.

89 W. Wallace, 'Post-Sovereign Governance', in *Policy-Making in the European Union*, H. Wallace, W. Wallace, and M.A. Pollack (eds) (5th edn, Oxford, Oxford University Press, 2005), p. 495.

90 Sideri (2007). In the case of the software patent this meant that the logic of property rights was the sole frame of reference for DG Internal Market, which was quite alien to many of the free software activists who thought more in terms of pragmatic rationality, a view partly shared by DG Information Society.

process. This can be done through public consultations but also through more structured means, such as citizens' panels or giving stakeholders a seat at the table in working groups. Participatory lawmaking is linked to 'thin proceduralization' namely involving 'participation in which preferences remained exogenous, unchanged, and which is discourse-less'.[91]

II.2.6 Deliberative lawmaking

This model – which could be dubbed 'participatory lawmaking plus' – is the one Verhoeven proposes as the main alternative to the other more traditional models she mentions (regulatory, intergovernmental and parliamentary).[92] Deliberation is presented as the antidote to harmful bargaining. The founding father of deliberative lawmaking is the German philosopher and sociologist Jürgen Habermas. Deliberative lawmaking can be placed within the tradition of proceduralism and is characterised by the fact that it does not focus on the state, institutions or rights. Applied to lawmaking this means that procedures by which legislative decisions are reached should be as non-hierarchical as possible and designed so as to maximise opportunities for deliberation. Deliberative lawmaking relies on democracy 'in accordance with the discourse principle, involving duties of reciprocity and civility and the use of public reason'.[93] The model is not tied to any particular substantive regulatory goal. Any objective that is proposed in the lawmaking process should be subject to discussion between relevant stakeholders.

The deliberative model can be distinguished from the participatory model by its higher demands on participants and the stricter rules of the game. Both focus on procedure without relying on traditional constitutional mechanisms and value 'input' higher than 'output' but deliberative lawmaking needs heavier procedural standards. In deliberative lawmaking the effects of power inequalities should be minimised, so as to get as close as possible to the 'ideal speech situation' developed at the theoretical level by Habermas.[94] Some preconditions for approximating such a situation are:

- actors must demonstrate to put themselves in the position of the other participants in the deliberation;
- actors must share some degree of common background and values;
- open discourse with equal access for all actors.[95]

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91 J. Lenoble and M. Maesschalk, *Towards a Theory of Governance. The Action of Norms* (The Hague, Kluwer Law International, 2003).

92 Verhoeven (2002).

93 J. Black, 'Proceduralizing Regulation: Part I' (2000) 20 *Oxford Journal of Legal Studies*, 597-614.

94 Morgan and Yeung (2007), p. 37.

95 T. Risse, ''Let's Argue!' Communicative Action and World Politics' (2000) 54 *International Organization*, 10-11.

II.2.7 Judicial lawmaking

As mentioned, conceptualising judicial review as a complete model of lawmaking is far-fetched. Although the understanding that judges sometimes 'make law' when they are asked to interpret or invalidate legislative provisions is widely shared among lawyers,[96] few would actually speak of 'judicial lawmaking'. But the oft-heard argument that it is preferable to have broadly formulated provisions in a law that can then be interpreted – in accordance with fundamental rights and the constitution – by the courts, can amount to 'judicial lawmaking'. This model is linked to the 'juridico-administrative rationality' that Sideri has observed in her case-study of the 'software patent saga'.[97] It means that the very early thinking among many Commission officials already revolves around legal measures and builds on existing legal concepts, such as 'intellectual property' rather than concepts such as 'innovation' or 'competitiveness'. The latter concepts are not easily amenable to judicial review, which in this model is considered to be the ultimate quality control. The legalistic reasoning as the dominant mode of thinking may also lead to placing an emphasis on the connection between 'Better Regulation' and 'better legislative drafting'.

Table II.1: Overview of the models and related values

Models of lawmaking	*Legitimacy*	*Main underlying concept*	*Associated type of decision-making*	*Associated values*
Parliamentary	Input	Democracy	Political	Majoritarianism Legislative mandate
Intergovernmental	Input	Democracy	Consensus	Nation state
Participatory	Input	Procedure	Consensus Political	Participation Responsiveness
Deliberative	Input	Procedure	Consensus Evidence	Deliberation Responsiveness
Regulatory	Output	Procedure/ Ratio	Expert Evidence	Expertise Efficiency Legislative mandate
Bureaucratic	Output	Ratio	Evidence Benchmarking	Efficiency Effectiveness
Judicial	Output	Constitution	Fundamental rights Political	Individual freedom Deliberation

96 K. Malleson, *The New Judiciary: The Effects of Expansion and Activism* (Aldershot, Ashgate, 1999).

97 For research on IA, the software patents is a non-case: the proposal was developed before IA became obligatory and it was not selected for the pilot phase.

Figure II.2 Models of lawmaking and legitimizing values

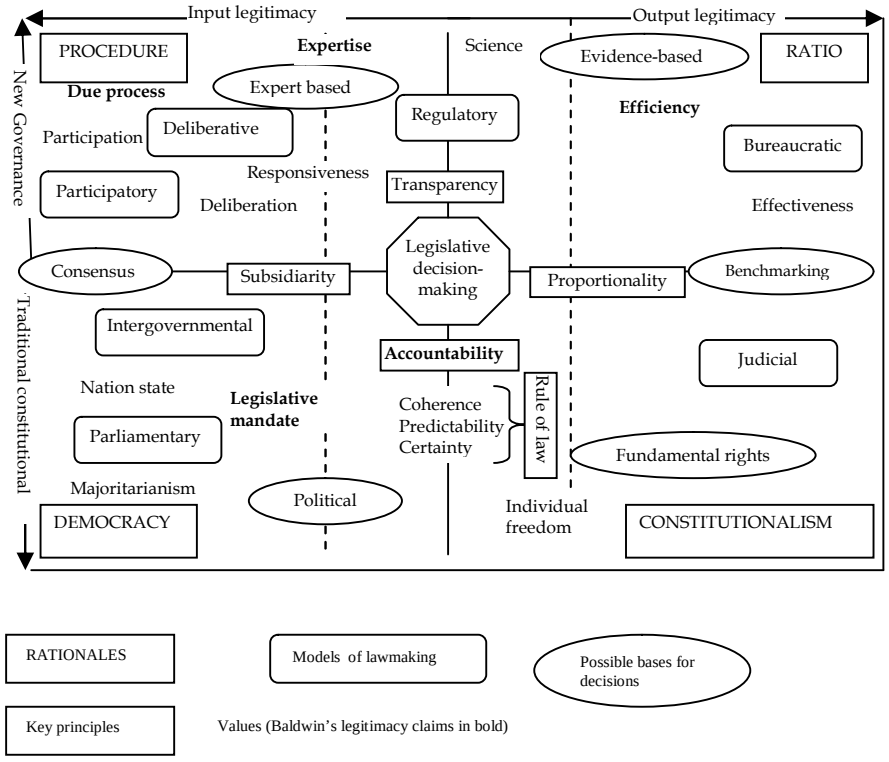

Figure II.2 above graphically presents the relations between different values and models of lawmaking by placing them on two axes: one indicates whether they rely more on input legitimacy or output legitimacy and to what extent, the other places them in either the traditional constitutional law or the discourse of new governance.

II.3 'INFORMING' THROUGH IA: A TYPOLOGY

> [To] provide the legislator with more accurate and better structured information on the positive and negative impacts, having regard to economic, social and environmental aspects.

Proclaiming 'information' as the overarching function of impact assessment makes it easier to reach agreement between various stakeholders on the desirability of the tool, because of its strong connotation with 'objectivity' and 'neutrality'. Yet, paradoxically, the central function of disclosing information

to decision-makers also presents a problem for the tool in terms of legitimacy. Impact assessment was originally designed to go beyond mere information provision by ensuring that regulatory benefits exceeded the costs and were maximised were possible. But even if one accepts that we now have an 'informative', European type of IA, the question remains what exactly 'informing the legislator' means in practice. The phrase implies a very humble and neutral role, but – as shown below – there is more than one way of interpreting the concept of 'informing'.

IA is designed to handle regulatory trade-offs, but there are trade-offs in its own design as well. Below five ideal-typical modes of use of IA are discussed, all theoretically feasible in the EU context, characterised by a slogan-like expression of their core function. The idea of devising models of IAs is inspired by the National Audit Office (NAO) Evaluation of Regulatory Impact Assessments 2004-2005 in which three types of IAs were distinguished.[98] However in that report the three approaches (pro-forma IA, informative IA and integrated IA) represent different degrees of quality whereas the ideal-typical IAs here do not necessarily imply any judgment on their merits. Although the discussion of the models throughout the thesis will occasionally be of an evaluative nature, the typology first and foremost serves to describe possible approaches to IA as an instrument in the legislative process in a systematic way.[99] The basic presumption is that each type of IA presented below can be implemented in good and bad ways. Which model is the 'best' depends on what a polity wants out of IA as a tool as well as on the degree of 'fit' with the wider institutional environment.

II.3.1 'Speaking truth to power'

> The purpose of impact assessment is to compare a legislation approach with non-legislative approaches and weigh up the costs of regulation against the benefits.[100]

The vision implicit in this statement by the UK government implies that an impact assessment contains not only an analysis and comparison of policy options but also a judgment on which policy options can best be justified. In such a vision the idea contains more than objective data, it issues a recom-

98 National Audit Office (2005).

99 I am grateful to Claudio Radaelli for pointing out that there are (at least) three ways in which to use typologies: to describe something in a systematic way, to explain a phenomenon or for the purpose of normative appraisal (e.g. the NAO models). This thesis will mainly make use of the first application: systematic description.

100 UK Government's Response to House of Lords 31st report (2005), appendix 1, para. 61.

mendation and as such is 'speaking truth to power'.[101] The idea of 'speaking truth to power' is certainly not new. Ever since the expression was coined by Wildavsky in the late nineteen seventies, it has popped up every now and then in discussions on IA and on the role of analysis in decision-making more broadly. Its roots lie in public choice theory which assumes that in the end all regulation is the product of rent-seeking by stakeholders (private or public) and the only thing we can do to counter this is make an objective economic analysis which lays bare *all* costs and benefits of the proposed legislation, including those that interest groups would rather conceal.[102] The identification of 'correct' decisions is also the original function of IA when it was developed to rationalize planning decisions. Speaking truth to a legislator is another matter however.

In the real world most people would dismiss a 'truth to power' application of IA as a 'rationalist fantasy'. Information cannot be perfect and political decision-making cannot be declared irrelevant without running into enormous legitimacy problems. But even if this is a model many would reject when spelled out, it is still the implicit theoretical assumption underpinning many forms of appraisal and certainly IA. Also in the EU context, the idea that IA can speak truth to power is appealing and is often present in the discussion on the development of the IA regime albeit in a more moderate institutional dress-up.

Within this model variations are possible as to who speaks and who the power who listens is. Applying the model as a framework to the US system for instance, it is the politicians who want to use 'truth' to keep the delegated 'power' of regulatory agencies in check.[103] However, using IA as a means of exercising control over delegated rule-making competences is not the first function that comes to mind for the EU context in which IA is meant to function in the primary legislative process. Or is it? One way to think about the way the EU has acquired its powers is as delegation by national states to a (special kind of) international organization. And indeed, it was the Member States who initially pressed for the use of IA in the European legislative process and they

101 The famous catch phrase 'speaking truth to power' is the title of a book on policy analysis written by Aaron Wildavsky in 1979. The book describes the state of the art of the field of policy analysis in its early days and proposes how to establish policy analysis as a discipline in its own right. This should not be taken to mean that Wildavsky believes policy analysis amounts to 'speaking truth to power'. After mentioning the phrase for the first time in the introduction he even adds between brackets the exclamation 'if only we had either!'. Indeed, he insists that policy analysis is about "relationships between people". A. Wildavsky, *Speaking Truth to Power: The Art and Craft of Policy Analysis* (Boston, Little Brown, 1979), pp. 1 and 17.

102 The classical study is by W. Niskanen (1971), *Bureaucracy and Representative Government* (Cheltenham, Edward Elgar, reprinted in Bureaucracy and Public Economics, 1996).

103 See e.g. E.A. Posner, 'Controlling agencies with cost-benefit analysis: a positive political theory perspective', John M. Olin Law and Economics Working Papers 2nd series no 119 (Chicago, 2001).

are among those calling for enhanced use of external expertise.[104] But the specific use of IA at the EU level throughout the primary legislative process also allows to point to a different variety of the truth to power model. Here 'truth' could be provided by the administration responsible for the preparation of legislative proposals and it is up to the political 'power' in its capacity of legislator to listen. This variety comes quite close to the presentation of the IA system by the Commission. However, it does not sit comfortably with the political role that the Commission also has, most notably expressed through its exclusive right of initiative. And what if the legislative mandate is formulated in terms other than efficiency, as is often the case?[105]

'Substituting political decision-making' is both the danger and the appeal of this model. For when an IA is perceived as containing the objective truth, the only way it can justify a regulatory decision is when this decision follows the recommendations that the IA report inevitably contains, turning IA effectively into a 'decision-making tool'. Returning to the discourse of the Commission, 'speaking truth to power' is visible in a limited sense when IA is presented as 'a means of selecting, during the work programming phase, *those initiatives which are really necessary*'.[106] The qualification 'during the work programming phase' means that it is more a matter of self-imposed discipline than a means of substituting the legislative process, but the verb 'to select' implies a mechanical process that does not involve political discretion on the part of the Commission.

II.3.2 'Reason-giving for legislative decisions'

If the models discussed in this section are placed on a scale of ambition the 'reason-giving' model would be at the opposite side from the 'truth to power' model discussed in the previous section. In this model IA is seen as a communication tool which helps politicians to convince stakeholders and citizens of the virtues of the legislation or policy at hand. This type of IA serves most and for all to justify legislative and policy decisions with the extent to which the analysis has influenced or guided the proposal remaining unclear. Although coming close to the 'pro-forma IA' in the typology devised by the NAO,[107] it does not carry the same negative connotation. As soon as an IA aimed at 'reason-giving for legislative decisions' is measured against the lower ambitions it carries, it becomes clear that it can be much more than a mere

104 Six Presidencies Joint Statement (2004).
105 R. Baldwin and M. Cave, *Understanding Regulation. Theory, Strategy and Practice*, (Oxford, Oxford University Press, 1999), p. 89.
106 COM(2002) 275, p. 4.

symbolic exercise. This type of tool can be useful and legitimate and is even obligatory as a matter of constitutional law.[108]

Its worth in the EU context should not be underestimated either. Craig and De Búrca in their textbook on EU law remind us that the duty to give reasons for legislative decisions in Community law already goes further than in many national legal systems.[109] Because a 'reason-giving IA' tends to come later in the lawmaking process it allows for more detailed analysis. As such it can contain valuable information for judges and act as an interpretative tool that fits with the judicial lawmaking. A justifying document is more likely to be suited to help uncover 'legislative intent' than a 'challenging' IA that starts from 'blue skies thinking'.

The question remains what the difference is with an explanatory memorandum (see III.5.2). It is questionable whether it is still legitimate to call an IA which does nothing more that justifying decisions that have already been taken an 'impact assessment'. This term is normally associated with a higher level of ambition (at the very least the IA should *challenge* the decision-maker) and having mere 'reason-giving' as the core task of impact assessments could either lead to overselling explanatory memorandums or – in the long run – to inflation of the concept of IA. Baldwin's warning that IAs can come to serve as 'shields to allow decisions to be routinized, reasons for any findings to be produced with ease, and decision-makers to be both insulated from political pressures and lent authority for any particular exercise of power'[110] seems to have been made with this type of IA in mind.

There is however certainly a relevant sense in which this type of IA can contribute to Better Regulation. In its earlier days 'better lawmaking' was largely about speeding up the legislative process and strengthening the position of the Commission, as is evidenced by this wording from the 2002 Action Plan:

> [B]y giving the European Parliament and Council greater encouragement to come to an agreement quickly, in cases where this is appropriate, and to do so where possible during the first reading in cases where the codecision procedure is applicable. For this to happen, the Commission will have to be more systematically involved in the early stages of the negotiations. It will use the consultations and impact assessments it conducted earlier in order to rally support for its proposals.[111]

If the quality of regulation is seen to crucially depend on the efficiency of the lawmaking process itself and – perhaps more controversially – on an outcome that lies as closely to the original Commission proposal as possible, then a

108 Article 253 TEC.

109 P.P. Craig and G. de Búrca, *EU Law. Text, Cases and Materials* (Oxford, Oxford University Press, 2003), p. 117.

110 R. Baldwin, *Rules and Government*, (Oxford, Clarendon Press, 1995).

111 COM(2002) 278 final, p. 8.

mere 'reason-giving' IA could be appropriate. However, speeding up the legislative process, is certainly not the only aim of Better Regulation (BR). On the contrary, as the 2003 IIA was implemented, gradually BR became about cramming more elements into the legislative process instead, rendering the 'giving reasons for legislative decision-making' too simplistic a goal for the IA procedure.

II.3.3 'Providing a forum for stakeholder input'

'You need no competence to join in', Oliver Kamm wrote in an article on political blogs in newspaper The Guardian.[112] The same can be said about impact assessments. Every person or organization is free to produce a study on a problem of public policy and label it 'impact assessment'. The term carries no legal weight in and of itself and there are no rules of recognition associated with the process. That is music to the ears of those who subscribe to the pluralistic, participatory ideal. Stakeholders can produce their own impact assessment, but they can also take part in the assessment carried out by a public body, if only the process is open enough.

As with the previous model there is a tension with the roots of IA as an objective document. 'Providing a forum for stakeholder input' can mean that the IA report is reduced to a document summarising the consultation, whereas by any 'minimum' standard IA should provide at least some degree of objective, reproducible analysis. 'Informing the legislator' then means channelling the policy preferences of stakeholders. This approach to IA appeals to those who take a cynical view to IA's capacity to carry objective truths. What is left, then, is transparency in the policy-making process and input by other means than the traditional, representative ones. Appreciation of this model also critically hinges on how 'consultation' is understood. Is it brutal lobbying or rather 'an essential part of the policy-development process, enhancing its transparency and ensuring that proposed policy is practically workable and legitimate from the point of view of stakeholders?'[113] (see V.6.2).

II.3.4 'Highlighting trade-offs'

This model is a light-version of the 'truth to power' type of IA, but it starts from the conviction that 'it would be naive to think that 'informing' the legislature, 'guiding' regulatory decisions, and 'justifying' the choice of instruments

112 Oliver Kamm, 'A parody of democracy', The Guardian, Monday 9 April 2007, p. 19.
113 COM(2002) 704 final.

are politically neutral activities.'[114] It is still founded on the belief that objective analysis of problems in society and their proposed policy solutions is feasible, but it refuses to place all faith in cost-benefit calculations. The core difference with the 'truth to power' model is that the 'highlighting trade-off' model is most and for all aimed at holding legislators *accountable*. Speaking truth to power on the other hand can lead to all responsibility – and thereby all accountability – being taken away from the political decision-makers. After all, the IA tells them which solution to choose and thus becomes a shield to hide behind. By contrast, in the highlighting trade-offs model IA is a rational input into the decision-making process. That process may then go on to ignore the IA; that is all in the game. Not every decision would be directly justified by an IA, but on a macro level legitimacy would still be enhanced by the presence of the IA regime. The legitimizing function that IA can exercise within this model is clearly set out by Pelkmans in a critical piece on the REACH IA process:

> With good RIAs, decision-makers can be held accountable because the benefits, costs and trade-offs should be expected to have been set out clearly , and perhaps to some extent even quantitatively, in the RIA in an analytically respectable manner. Admittedly, this will never be without some problems, grey zones of uncertainty or degrees of reasonable differentiation because of the inherent difficulties of making an RIA. Still, it would be the best possible, based on rigorously defined methodology, and within the framework of the 'guidelines' (which are quite systematic). A proper RIA would truly shift the political responsibility to the decision-makers where it belongs. And in most cases it would be reasonable to expect that decision-makers would follow the course of a better balance between identifiable benefits and (now more explicit) costs for the European society at large.[115]

The greatest challenge for this model is the institutional design needed to make it work. How to 'inform' political decision-makers of the trade-offs in such a way that they can meaningfully take into account a decision without resorting to a truth to power model?

The main appeal of the 'highlighting trade-offs' model is that there is no need to make tough decisions about general decision criteria, but at the same time this poses a great risk. If there are no decision criteria, IA can more easily become a vehicle to continue regulatory capture but this time it can happen under a scientific guise. If the decision criterion is not contained in the IA

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114 R.A.J. Van Gestel, 'Evidence-based lawmaking and the quality of legislation. Regulatory impact assessments in the European Union and the Netherlands', in *Staatsmodernisierung in Europa*, H. Schäffer and J. Iliopoulos-Strangas (eds) (Athens/Berlin/Brussels, SIPE, 2007), pp. 139-165.

115 M. Citi and M. Rhodes, 'New Modes of Governance in the EU: A critical survey and analysis', in *Handbook of European Union Politics*, K.E. Jorgensen, M. Pollack, and B. Rosamond (eds) (London, Sage, 2006).

framework, where is it laid down? At some point in the process a decision criterion will still be needed, but it is not included in the IA framework. And if there is no decision criterion, what is the use of highlighting trade-offs when a politician can just ignore them?

On a first assessment this fits the EU context rather well as it is questionable whether the Commission would be competent to impose a meta-decisional criterion; the Treaty certainly does not contain a provision that charges the Commission of the EU legislator as a whole with – for instance – 'maximising the welfare of the citizens'. The model also sits comfortably with the predominant view in the European Parliament that '[e]ffective democratic accountability is only possible if Parliament has sufficient information on the consequences of legislation on social, economic and environmental aspects'.[116]

However the model also causes problems in the reality of the EU legislative process: what happens when the European Parliament or the Council want to use a different decision-making criterion than the Commission? If the 'highlighting trade-offs' model amounts to a compromise between the 'truth to power' approach and the 'reason-giving' approach, it also runs the risk of slipping into either. Can transparency ever be so strong that stakeholders will be able to distinguish between IAs that 'select', those that merely 'justify' and those that really 'inform' especially when it is – in the absence of any enforcement mechanisms – very easy to claim one thing and do the other?

II.3.5 'Structuring the discourse'

In this model the function of IA is to structure the discussion relating to the preparation of a proposal. But rather than seeing IA as a way of opening up the policy process as a pluralistic ideal,[117] this model ties inclusion in the debate to the quality of argument. Thus, this model is based on 'deliberative lawmaking' in the same way that the 'providing a forum for stakeholder input' model' leans on 'participatory lawmaking'. This type of IA is also aimed at arriving at one universally desirable solution but assumes that the only way to do this, is to implement a procedurally fair way to deliberate about that solution. When IA is presented as a means of structuring the 'discourse of justification'[118] it contributes to a proceduralization of the lawmaking process.

The IA framework would have to provide incentives for non-strategic arguing among legislative co-actors, thereby structuring the legislative discourse and contributing to a proceduralization of the lawmaking process. The following extract from the literature contains a clear plea in favour of the 'structuring the discourse' model:

116 EP Doorn report (2004).
117 Radaelli (2007), 200.
118 *Ibid.*, 203.

> Impact assessments offer private actors the possibility to intervene very early in the decision-making process. They create a new arena for policy deliberation, where the power of the better argument might influence the shaping. Early consultation can improve the available knowledge, help to identify problems such as unintended side effects and thus strengthen the overall quality of regulation. But it can also change the character of policy-formulation within the European Commission from technocratic problem-solving of Commission officials to either political bargaining with Member States or argumentative deliberation with stakeholders.[119]

Gehring has argued that the 'New Approach' to Single Market regulation 'appears to be generally capable of providing incentives for deliberative interaction'.[120] In theory Better Regulation can provide similar incentives '[w]ith its emphasis on open and transparent processes, disciplined consultation, fair treatment of the empirical evidence, robust and pluralistic peer review'.[121] This approach is vulnerable to all the familiar criticisms of the literature on deliberative democracy.[122] In any case clear and well-established rules are needed to prevent misuse and slipping back into strategic and/or bargaining mode and to ensure a non-hierarchical structure.

The deliberative doctrine has been used to defend the legitimacy of committee governance;[123] this thesis does not follow the same normative approach. Instead the aim is to show that the deliberative model provides one angle from which IA can be defended and shaped. Furthermore, deliberative elements will be traced in the case studies.

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119 C. Hey, K. Jacob and A. Volkery, 'Better regulation by new governance hybrids? Governance models and the reform of European chemicals policy', Environmental Policy Research Centre FFU-report 02-2006 (Berlin, 2006).

120 T. Gehring, 'Institutional Stimulation of Deliberative Decision-Making: Technical Regulation in the European Union', ARENA Working Papers (Oslo, 2007), p. 29.

121 COM(2003) 770 final, p. 3.

122 Although deliberative theory is usually criticised on the grounds that it is not feasible, sometimes itsintrinsic worthiness is challenged on the grounds that it is not democratic.

123 C. Joerges and J. Neyer, 'From Intergovernmental Bargaining to Deliberative Political Process: The Constitutionalization of Comitology' (1997) 3 *European Law Journal*, 273-299.

Table II.2: Overview of the types of IA

Model	*Meaning of 'to inform'*	*Dominant values*	*Model of lawmaking*	*Link with constitutional level*
Speaking truth to power	To dictate	Expertise Transparency Accountability	Bureaucratic Regulatory	Potentially problematic: strong control outside the Constitution?
Reason-giving for legislative decisions	To justify	Accountability Discretion	Judicial Intergovernmental	Elaboration of Treaty objectives + Implementation reason-giving obligation
Providing a forum for stakeholder input	To facilitate	Transparency Direct democracy	Participatory	Implementation of participatory rights
Highlighting trade-offs	To guide (substantively)	Discretion Evidence-base	Regulatory Parliamentary	Can cause inter-institutional conflict
Structuring the discourse	To guide (procedurally)	Due process Consensus	Deliberative	'Thick' procedural rules needed (currently lacking)

II.4 CONCLUDING REMARKS

This chapter has outlined the development of the EU Better Regulation strategy against the background of its main concerns: a) enhancing legitimacy (of various kinds) whilst b) taking account of the conditions of EU lawmaking (in particular the institutional balance). It has also laid the foundations for the following chapters by developing seven models of lawmaking which each depend on a set of interrelating values. In a final step these models have been translated into five types of IA, each with a different core function which represents one interpretation of 'informing the legislator'. These models of lawmaking and types of IA will be used extensively throughout the rest of the thesis as interpretative devices which can help structure both the content of various policy documents and the empirical material.

III IA in the European Commission

This chapter sets out the Commission's overall approach to IA as well as some details of the development of the Commission IA procedure from 2002 until the summer of 2007.

III.1 Developing IA policy in the Commission

III.1.1 The 1990s: specialised assessments

Ex ante evaluation of policies and laws is common practice in administrations all over the world, occurring in many varieties and different degrees of implementation. The European Commission too was using early-stage assessments of its draft proposals long before it adopted the integrated IA procedure in 2002. Examples are business impact assessment (BIA) which was introduced in 1986, sustainability impact assessment (SIA) and impact notes. These tools have in common that they can be classified as 'special impact assessment instruments'. The occasional 'regulatory impact assessment' was made, but bore hardly any resemblance to the new impact assessment template and the effectiveness of these tools has been questioned.[1] As an illustration, the European Parliament noted that the system of impact notes 'has supplied no information that has been helpful in assessing the consequences and costs of proposed European legislation'.[2] Other types of assessment are very specific or limited in scope. Their remaining relevance after the introduction of integrated IA is discussed in section III.5.2. The business impact assessment (BIA) – introduced in 1986 as part of EC economic policy and strongly focussed on costs to business – was entirely replaced by IA. In an evaluation of this system, BIA was considered to be too limited in its scope, to have been used in an arbitrary way and to possess a tendency to oversimplify matters. The findings of this evaluation led to recommendations for an integrated IA system.

1 Radaelli (2007).
2 EP Doorn report (2004), p. 5.

III.1.2 The institutional context of Commission IA

A representative statement on the multiple goals of the impact assessment regime in the view of the Commission can be found in the Work Programme for 2006:

> Impact assessment ensures that policy is made in full knowledge of the facts and awareness of the implications. It also guides the policy-making process through an open analysis of the options and provides a discipline to ensure that economic, social and environmental factors are fully taken into account, including the impact on competitiveness. The impact assessment should also guide the inter-institutional decisionmaking process and it provides a clear and accessible public explanation of why a proposal is being made.[3]

The Commission's power in the legislative process stems from its exclusive right to propose legislation. In the Communication on 'European Governance: Better lawmaking' the Community method was called 'the very basis of the European Union'[4] and praised for its flexibility, which had been called upon by the introduction of 'European governance. The Commission's right of initiative was presented as 'the cornerstone of the Community method' and as such it is 'the indispensable counterpart to majority voting in the Council, in as much as the Commission's right of initiative guarantees vital minority interests when it comes to defining the general interest.'[5]

Scharpf has pointed out that a 'revitalization of the Community Method'[6] as the Commission proposed in the White Paper on Governance,[7] comes down to a strengthening of its own role in the legislative process.[8] This proposal is accompanied by 'the implicit assumption that the Commission itself is somehow also a beneficiary of democratic legitimacy'.[9] Scharpf goes on to suggest that in normative debates this claim is generally assumed to be incompatible with another claim the Commission has repeatedly made, namely to play the role of a politically neutral promoter of the European common interest. Although these debates focussed on the question whether the Commission should be granted more autonomous policy and rule-making power, the two

3 COM(2005) 531 final, p. 11.
4 COM(2002) 275 final, p. 6.
5 COM(2001) 428 final, p. 29.
6 R. van Schendelen, *Machiavelli in Brussels. The Art of Lobbying the EU* (Amsterdam, Amsterdam University Press, 2005), p. 68.
7 COM(2001) 428 final.
8 F.W. Scharpf, 'European Governance: Common Concerns vs. The Challenge of Diversity', MPIfG Working Paper 01/6 (Cologne, 2001).
9 F.W. Scharpf, 'European Governance: Common Concerns vs. the Challenge of Diversity', paper delivered to the symposium: Mountain or Molehill? A Critical Appraisal of the Commission White Paper on Governance (Florence, 2002), p. 22.

allegedly incompatible claims can be uncovered in the Commission documents on the IA procedure as well.

'Guardian of the Treaties' and 'guardian of reason'?

The idea of objective impact assessments is linked to the image of the Commission as an independent guardian acting in the general interest of the Community. The Commission is the guardian of the Treaties, the initiator of proposals for legislation and the executor of EC policies. The latter function is not very relevant here, but the first and the second are. The two roles of 'guardian' and 'initiator' together make for the very unique kind of political role the Commission has been assigned and also seems to envisage for itself, namely that of a political guide. However:

> There is a wide gap between the Commission's self-perception of its role, as guardian of the treaties and agenda-setter, and outside perceptions of its weaknesses as policy manager.[10]

The Commission has been accused in the media of unwillingness to 'disavow its regulatory lusts.'[11] A large part of Better Regulation can be seen as an effort to counter perceptions that the Commission is some kind of self-interested bureaucratic monster. The Commission views itself rather as a 'scapegoat for poor legislation':

> Since it is being held responsible it can not escape acting responsibly. This means the following:
> - the Commission has to have the courage to block unjustified regulatory initiatives from other actors
> - the Commission has to anticipate regulatory criticisms by extending its explanatory memorandum practice
> - even the preparatory legislative process has to be transparent.[12]

When the policy documents on IA speaks of 'informing the political level', the political seems to refer to the internal political level: the College of Commissioners. They are the first ones who have to be informed by the IA. One of the best ways to ensure that the IA does come to dictate the political decision, is to thoroughly analyse several options and to refrain from concluding at the bureaucratic level that any one of those would be the best solution to the problem. If the IA is merely highlighting the trade-offs (see II.3.4) across a number of options, the political level can take responsibility for the choice. Although this approach is the most logical one, in view of the internal institu-

10 Wallace (2005), p. 496.
11 'We'll do better next time', The Economist (London, 2001).
12 EC Report on 'Evaluation and Transparency' (2001), p. 3.

tional structures of the Commission, the question remains whether too much emphasis on the 'highlighting trade-offs model' will do anything to counter the various perceptions of the Commission as 'regulatory monster' (regardless of the accuracy of these perceptions). To this end providing 'a discipline to ensure that economic, social and environmental factors are fully taken into account'[13] is a crucial element in the design of the IA system, but it is uncertain whether the 'highlighting trade-offs' type IA is able to provide it.

Protecting the right of initiative

For the Commission, IA can serve as a device to fence off requests for legislation from lobby groups, Member States[14] or other Community institutions, for it can now point to the fact that even if there is no formal requirement for the proposal to be in line with the IA, certain reasons for intervention will look particularly bad in an IA report. Protecting its right of initiative by trying to keep stakeholder involvement in policy making restricted to the formal channels as much as possible is also a reason for resisting pressure to publish the IA, or a draft version of it before the proposal is ready.

Internal coherence

> The Commission tends to legislate within silos.[15]

Obviously the Commission does not always speak with one voice. Since IA accommodates many different and often competing interests, it is only natural that different commissioners and DGs will have a different focus. Perhaps an official at DG Environment will not recognise himself in this remark by Günter Verheugen:

> We will only put forward proposals that have undergone an impact assessment. This approach should guarantee that we know the full costs and benefits of future legislation.[16]

Then there is the fact that the success of a Directorate-General used to be measured in terms of its regulatory output (quantitatively speaking rather than

13 COM(2005) 531 final, p. 11.

14 Majone has wondered why policy innovation is even happening in view of the fact that the member states dictate to such a large extent the policy agenda of the Commission. Majone (1996).

15 Arlene McCarthy, MEP, see A. McCarthy and M. Frassoni, 'Time to take a scalpel to the EU's regulatory fat?' European Voice (Brussels, 2005). By this she meant that within the legislative process the Commission officials involved in drafting a proposal do not always take into account the cross-departmental aspects.

16 House of Lords 9th report (2005), 25 of the Minutes of Evidence.

qualitatively)[17] has lead to an instinctive resistance to Better Regulation with some officials, who fear that the BR strategy is essentially 'anti-regulation'.

Stakeholders concerns

The main risk that stakeholders see is that since the Commission has no formal powers to make law, it could use IA as a way of having a greater say about the final content of the legislation. The argument is that because the Commission has greater resources to conduct the necessary analyses than the other Institutions or actors, it could use IA to consolidate its power base in an era of evidence-based decision-making. Stakeholders may share the fear of the Commission using the IA procedure for its own purposes, they will differ on the question of whether this will lead to a pro-regulation attitude or a pro-business attitude. The Commission is sometimes said to be biased towards legislative solutions because from 'production' of legislative proposals it derives an important part of its power, as is illustrated by the following quotation:

> The Commission should focus less on grandiose statements and more on the need to change its own culture, which is used to responding to every problem with a directive or a regulation, regardless of whether it is the right solution. The introduction of impact assessments will assist in bringing forward a more informed analysis of new EU laws.[18]

The following quote however demonstrates that others are afraid that Better Regulation will lead the Commission to take *too little* action and IA can be an impediment to much needed legislation.

> Better regulation is a noble and important concept to fight for. But the quality of regulation is still first and foremost a function of informed and vigorous political action. And as long as the Commission uses the tools of the 'better regulation' initiative as an excuse to avoid, prevent, or bypass that political debate to the benefit of corporate interests, the initiative will do precious little to reassure Europe's citizens.[19]

Regardless of the political colour, it is clear that the 'legislative burden of proof' expected by all actors is becoming heavier. In that respect representatives of national government have for instance pointed at the importance of the Commission improving the subsidiarity test within the IA procedure.[20]

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17 Stanley Crossick at EPC forum on 'Better Regulation and the transatlantic dialogue'.
18 McCarthy and Frassoni (2005) (contribution MEP Arlene McCarthy).
19 *Ibid*. (contribution MEP Monica Frassoni).
20 Dutch Minister Atzo Nicolaï at the Conference 'Sharing Power in Europe', 17 November 2005, The Hague.

III.1.3 Increasing institutionalisation

After the pilot project in 2003 and 2004 the Commission's IA system has gradually matured and developed into a force in policy-making processes that can no longer be ignored. This section aims to give an impression of the degree of institutionalisation by highlighting two illustrative elements: the 2005 Guidelines and an overview of the number of IAs produced. A third significant factor in the ongoing process of institutionalisation, quality control, is discussed in section III.4.

The IA Guidelines

For the pilot project a set of IA guidance, consisting of a set of three documents was developed.[21] As part of an internal stock-taking process in late 2003 and early 2004 by the 'IA working group' consisting of representatives from the DGs that took part in the pilot phase most actively (ECFIN, MARKT, ENTR, ENV and EMPL), these guidance documents were subjected to a thorough revision. The intention was to produce one comprehensive set of guidelines and the ad hoc working group received a mandate from Directorates-General for proposing such new IA guidelines. After a revision process of several months, coordinated by the Commission's Secretariat-General and followed by quasi-political endorsement of the Guidelines by the College of Commissioners, the new guidelines were published on 15 June 2005. The Secretariat-General received a mandate to 'update'[22] the Guidelines, which has so far been used once, in March 2006, mainly to incorporate the methodology for measuring administrative burdens as part of IAs (see III.5.1). Before their content is discussed (see III.2 and III.3), the status and role of the Commission IA Guidelines in shaping the IA system are addressed.

The Guidelines have the legal form of a Staff Working Document. There is no legal obligation to make documents of this type public, but in many cases – as happened in this case – they are published on the web as a matter of transparency.[23] The TEP evaluation (see III.4.3) concluded that the Guidelines are seen more as an introduction to the IA process than as a helpful tool for carrying out IAs in practice.[24] Indeed, here and there – particularly in the Annexes – read as an 'introduction to regulation theory', this time not written by Baldwin and Cave,[25] but by the Commission services. However it is sub-

21 IA Guidelines (old version) (2002).
22 To call it anything else than an 'update' would have meant giving the document a new reference number.
23 The degree of transparency surrounding the IA procedure is enormous compared to other Better Regulation projects, such as the screening exercise, for which no guidelines exist or criteria have been published.
24 The Evaluation Partnership (TEP) (2007), p. 53.
25 Baldwin and Cave (1999).

mitted that the Guidelines need to be 'abstract and theoretical'[26] to a certain extent, because a change in the legislative culture can never be build on checklists and practical examples only. The question to what extent desk officers are able to 'pick and choose' from the Guidelines is likely to be resolved once the Impact Assessment Board (IAB) establishes itself more firmly.

A separate issue is to what extent the Guidelines have shaped the expectations among various stakeholders as to how the IA procedure is implemented by the Commission. As such, the Guidelines can be seen as an interpretative document setting out how the Commission views the role of legislation in the EU and its own role in the legislative process. The importance of the Guidelines as a defining document should not be overstated. They do not represent the definitive framework for the production and use of IA in the European legislative process. It is a document produced under time pressure which contains many compromises between different parts of the Commission services. The Guidelines do however provide the most detailed insight available into how the Commission plans to use IA. One striking observation from the various – predominantly positive – stakeholder reviews of the Guidelines is that commentators tend to see their own image of impact assessment confirmed.[27]

Increasing visibility: some numbers

The development of Commission IA in numerical terms is considerable. In the pilot phase which lasted from 2003 until 2004 the Commission managed only to complete about half of the impact assessments planned although the number increased from 21 to 29 in the second pilot year (2004).[28] Numbers rose steeply in 2005 (73 IAs) and 2006 (67 IAs) with the total number of IAs carried out now approaching exceeding 250 (of which 233 were published on the Secretariat-General's dedicated website as of 18 July 2007).[29]

26 The Evaluation Partnership (TEP) (2007), p. 53.

27 E.g. an article in the online magazine Euractiv states that "compared to previous versions, the new impact assessment guidelines stress the relative dominance of economic performance and competitiveness over social and environmental aspects." Euractiv, Better Regulation, published on 17 August 2004, updated on 8 April 2007, http://www.euractiv.com/en/opinion/better-regulation/article-117503 (last accessed 15 July 2007).

28 SEC(2004) 1153, p. 6.

29 The number Secretary-General Catherine Day mentioned in her speech of 28 June 2007 was 230 IAs. A count of the IAs mentioned on http://ec.europa.eu/governance/impact/practice_en.htm (last accessed 18 July 2007) raises the total number to 254, although 21 of those are not yet published and are marked as 'to be adopted'.

III.2 RULES ON SUBSTANCE

The rules on IA in the EU legislative process are laid down in different documents, none of them externally binding in any strong legal sense. Apart from the various policy documents and the IA Guidelines mentioned above, the main sources are the Inter-Institutional Agreement and the Inter-Institutional Common Approach.[30] In this section the structure of the Guidelines in explaining the standards and rules is roughly followed but other sources are drawn upon as well.

The Guidelines present the Commission's impact assessment procedure as a set of key steps that an official should follow once confronted with a problem that *may* require a regulatory solution. The emphasis is on the word 'may' here as the Guidelines stress that non-action is the default situation. In other words: the expediency of Community action is always to be questioned. Although there is a logical order to the key steps the Guidelines also point out that IA is also an 'iterative process',[31] meaning that many analytical steps will have to be revisited as a consequence of possible findings in a later stage of the process.

III.2.1 Principle of proportionate analysis

An important meta-principle in the IA procedure is the principle of proportionate analysis, not to be confused with the substantive proportionality principle which is enshrined in the Treaty. The principle of proportionate analysis stipulates that

> the impact assessment's depth and scope will be determined by the likely impacts of the proposed action (…). The more significant an action is likely to be, the greater the effort of quantification and monetisation that will generally be expected.[32]

In practical terms this means that Commission IAs will vary considerable in length, and methodology. The Guidelines provide some guidance as to what kind of proposals will normally need which degree of depth. For new regulatory proposals a particularly developed IA will usually be expected with special attention for the subsidiarity and proportionality check. When a proposal is aimed at revising existing legislation the required depth and scope will depend on whether the circumstances and the objectives of the legislation have changed. Evaluations of the existing regulatory framework will have to

30 Common Approach to Impact Assessment (2005); Inter-Institutional Agreement on Better Lawmaking (2003); SEC(2005) 791.
31 SEC(2005) 791, p. 8.
32 *Ibid.*, pp. 16-19.

be taken into account and alternative options will still have to be considered where appropriate. For broad policy-defining documents such as White Papers or Action Plans a broad description of the problem and objectives will often be the focus of the IA. However, mapping of possible courses of action envisaged to reach these objectives should be sufficiently detailed for stakeholders to prepare for possible consultations on these. Although any preliminary analysis of impacts will not be very detailed an effort to quantify these impacts should still be made; in line with the general guidance on whether to quantify. For expenditure programmes in many cases a combination of an ex ante evaluation and an impact assessment is foreseen (see III.5.2).

The principle of proportionate analysis has been made a central issue in the TEP evaluation (see III.4.3), which reported that this principle is seen as 'one of the keys to the success of the IA system' but also as 'one of the biggest problems on a daily basis'.[33] The evaluation report revealed that 'no DG has developed a more formalised definition of the principle of proportionate analysis'. As for informal criteria, TEP concluded the following:

> The research carried out during the evaluation has shown that the way the principle of proportionate analysis is interpreted and applied in individual IAs is generally the result of a number of interacting factors, processes and constraints, rather than of an explicit attempt to define the 'proportionate' depth and scope of the analysis in accordance with any pre-established criteria. Generally, the criteria applied informally are the magnitude of the likely impacts, but also more practical considerations, such as the available time, resources, tools and methodologies for quantification, as well as (in some cases) political considerations and sensitivities.

This shows how easily the principle of proportionate analysis can slip into mere convenience in its practical implementation.

To what extent the principle of proportionate analysis is prone to confusion was ironically illustrated in the methodology of the TEP evaluation itself. The consultants involved in the study assessed for each key part (problem definition, objectives, development of policy options etc.) of all 20 individual Commission impact assessments whether the analysis was proportionate. They judged compliance with the principle of proportionate analysis taking into account the following factors, which were clearly derived from the Guidelines (see III.2.1):

- Type of proposal and point in the policy-making process;
- Significance of the likely impacts (the more significant the impacts are likely to be, the more developed the analysis is expected to be);
- Available information, data and analytical tools.

Although this is certainly an inventive approach to a notoriously difficult to measure concept, it also leads to muddling a lot of different issues. A general

33 The Evaluation Partnership (TEP) (2007).

quality assessment, on the basis of a variety of unspecified criteria seems to have been carried out under the guise of proportionality evaluation. Consider the following examples.[34] The 'proportionality checkmark' for the TEP case study on the Directive laying down rules on nominal quantities for pre-packed products (see also the case study on the same proposal in this thesis VII.1) gives the following result for the stage of 'problem identification':

> This aspect of the IA is deemed not proportionate given that it does not provide a clear idea of the issue being addressed.

On the 'overall balance of the assessment of impacts' it states:

> This aspect of the IA is deemed partly proportionate given that the lack of a systematic analysis of a potential social impact has been criticised.

TEP concludes on the 'setting of objectives' as part of the case study on the Thematic Strategy on Air Pollution (see also the case study on the same proposal in this thesis VI.2):

> This aspect of the IA is deemed proportionate given that the examination of objectives is in line with the purpose of the proposal.

These judgments seem to deal with the consistency of the assessments, the issue of whether they stand the test of stakeholder criticism and the compliance with the IA Guidelines, but it is hard to see how this inductive approach can contribute to assessing compliance with the principle of proportionate analysis properly speaking. It seems more appropriate to take a deductive approach, in which a judgment is made ex ante regarding the expected depth of the IA, given the type of proposal, significance of likely impacts and time frame (the three factors mentioned above, all of which can be assessed independently of the actual IA report) and compared to the actual, overall assessment.

III.2.2 Problem identification

Academic literature has held for some time now that good problem analysis is central to 'regulatory craftsmanship'.[35] Indeed, the first step for all IAs according to the Guidelines involves analysing the issue/problem, including the causes behind it and the groups in society it affects primarily. Already

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34 All examples taken from The Evaluation Partnership, 'Evaluation of the Commission's Impact Assessment System. Annexes to the Final report (quality assessment reports)', SG-02/2006 (Brussels, 2007).

35 M.K. Sparrow, *The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance* (Washington DC, The Brookings Institution, 2000).

at this very first step of the analytical process that is impact assessment, the official conducting it should ask the question whether the EU level is the appropriate level to deal with the problem at hand. Thus, in accordance with some theoretical recommendations, the principle of subsidiarity is addressed in the earliest possible stage.[36]

The new Guidelines distinguish two main stages in the subsidiarity test. The necessity test has to be looked at in the very early stage of problem identification ('is the problem of such a nature that the Member States cannot solve it?'). The added value test can only be dealt with once the impact of the policy options are known ('is there at least one policy option that has a clear added value?'). A third test, the boundary test, consists of verifying that the proposed action does not go beyond what is authorized by the principle of subsidiarity. These two latter tests should be addressed at the stage of the comparison of options (see below).

III.2.3 Defining objectives and identification of policy options

The second step is to define some key objectives to tackle the problem and ensuring that these are consistent with other EU policies and strategies, such as the Sustainable Development and Lisbon Strategies. Objectives have to be 'SMART' (Specific, Measurable, Accepted, Realistic and Time-dependent).[37] The third step is looking at possible policy options to meet the objectives. In this phase the Guidelines advise to always consider the option of taking no action at all at EU level and to at least examine alternative approaches to legislative actions. First the policy options which could meet the objectives have to be identified, whilst considering 'the most appropriate delivery mechanisms'. The Guidelines point at the inter-institutional dimension:

> It is important to examine closely options that can count on considerable support. The other Institutions are responsible for carrying out impact assessments on amendments to Commission proposals. Nevertheless, it is very useful in terms of facilitating the legislative process if the Commission's impact assessment has already sought to anticipate the likely shape of the amendments from Council and Parliament.[38]

To what extent can IA really be useful as a tool to help determining whether regulatory intervention is appropriate? The OECD recommends RIA only as an instrument for after the decision to take action has been taken,[39] but the Commission system assumes that IA can play a role here. The 'no action' option

36 SEC(2005) 791, p. 21.
37 *Ibid*., p. 24.
38 *Ibid.*
39 OECD (2001).

– describing the problem as it will develop when no intervention is made – should not just be explored as a baseline measurement and as part of the problem definition, but should be evaluated in the IA as a potentially viable policy option. As a logical consequence of this, the IA guidelines stipulate that an impact assessment report also has to be completed 'in those cases where a decision is taken, possibly as a result of the impact assessment, not to proceed with the proposal'. The choice of instrument comes later (see III.2.5) and is placed under the heading of proportionality testing, not subsidiarity as the Amsterdam Protocol on subsidiarity suggests.[40] The list of options then needs to be narrowed down by means of screening for technical and other constraints, and by measuring against criteria of effectiveness, efficiency and consistency. Finally – according to the ideal template recommended in the Guidelines – a shortlist of potentially valid options is compiled for further analysis.

The distinction between the problem definition and the policy objectives is crucial, but – as becomes evident from a survey of IA practice and also from the case studies in chapters VI and VII – one that is hard to maintain. A final potential problematic issue is that the word 'option' is susceptible to multiple interpretations. Some will think of substantive, detailed options within a certain policy framework, others will think in terms of rough options (no action, financial incentives, regulation etc.), whereas a legal perspective in turn may point to the choice between different legal instruments (regulation, directive etc.). The issue has been clouded further by the renewed attention for the role of Better Regulation in improving the transposition and application of EU law.[41] In a recent communication the Commission has indicated that

> [i]ncreased attention should be paid to aspects of implementation, management and enforcement in the development of proposals, in particular at the impact assessment stage, and throughout the policy cycle. The impact assessment should examine implementation options and their implications, as well as the choice of legal instrument with a view to best facilitating the effectiveness of the measure.[42]

Examining the implications of implementation options suggests that the identification of the policy options takes place at a rather detailed level, which is at odds with the limited involvement of the Legal Service in the IA procedure (see also III.5.2).

A survey of IA practice shows that the content of the section on the 'main policy options available' varies from one impact assessment to another: sometimes different options consist of different regulatory techniques, at other times the main policy options listed are already quite specific. A clever middle way

40 SEC(2005) 791, p. 28.

41 See M. Kaeding, *Better regulation in the European Union: Lost in Translation or Full Steam Ahead? The transposition of EU transport directives across member states* (PhD thesis Leiden, 2007).

42 COM(2007) 502 final, p. 5.

can be found in the IA report on the reform of postal services regulation, where first four 'high level' policy options are presented which are then followed by a number of specific policy options within each 'high level' option.[43] Although a link between the level of abstraction of the main policy options and the timing of the IA might be expected, there is no evidence to suggest that IAs that were conducted later in the process contain more detailed options. In some cases 'late' IAs, such as the data retention IA[44] and the roaming regulation IA,[45] even resorted to the very basic level of options for regulatory intervention (self-regulation, co-regulation, soft law, market-based regulation etc.), only to claim that these options had to be discarded.

III.2.4 'Impact assessment' properly

The next step entails 'impact assessment' properly speaking. The new IA guidelines[46] propose rather than impose a list of impacts to be checked. However, the principle of proportionality will mean that not in every case each impact will have to be looked into with the same thoroughness, also because IA is meant to be more than 'checklist analysis'. When assessing the possible impacts of short-listed policy options, intended and unintended, across the social, economic and environmental dimensions, the list can serve as a reminder for officials that they have not missed a relevant impact category. One specific requirement that stands out here – because it suggests an interesting take on legitimacy in EU lawmaking – is that the analysis should also consider impacts that fall outside the EU.[47] Also, it should be noted that the list of impacts included types of impacts that are more difficult to measure by their very nature, such as public health impacts and certain long term environmental impacts. However, the IA framework includes an assumption that it is better to mention these, even if only a qualitative assessment can be given, especially if it is possible to estimate a margin.

Although impact assessment is often presented as or assumed to be synonymous with cost-benefit analysis, the European Commission IA system does not prescribe one methodology. Instead, the IA Guidelines leave it to the

43 SEC(2006) 1291.

44 This IA is elaborated upon in VII.2. The IA report started from the assumption that 'policy options' refers to different basic regulatory technique and mentioned self-regulation and soft law as policy options, although it was immediately added that these were discarded in an earlier stage already, see SEC(2005) 1131, p. 10.

45 SEC(2006)925. The regulation has been adopted in the meantime: Regulation (EC) No 717/2007 of the European Parliament and of the Council of 27 June 2007 on roaming on public mobile telephone networks within the Community and amending Directive 2002/21/EC, OJ L 171, 29 June 2007.

46 SEC(2005) 791.

47 *Ibid*., p. 37.

discretion of the desk officer that is preparing the IA to determine just how thorough the economic analysis should be and which type of economic analysis is most appropriate. In the Guidelines combining quantitative and qualitative methods is presented as 'good practice'.[48] The idea behind this is that overemphasizing the importance of quantitative analysis can lead to spurious accuracy. Possible methods include cost-benefit analysis, cost-effectiveness analysis, multi-criteria analysis and risk analysis.[49]

A cost-benefit approach should be distinguished from cost-benefit analysis in the narrow sense. The former is nothing more than using analytical method for assessing a proposal in terms of its consequences in a consistent manner, albeit one that accepts the logic of detrimental effects and beneficial effects. These effects can be described in qualitative terms or they can be quantified either in monetary terms (monetisation) or in some other way (e.g. lives saved per year). Whereas it is relatively common for an IA to follow a cost-benefit *approach*, in only a few cases a this is done by means of a cost-benefit *analysis*. The latter – in its full form – is an analytical tool originally used for decision-making on large infrastructural projects. Developing a cost-benefit analysis in such a way that it is accurate enough to quantify the effects of a decision reliably and comprehensively can take many years. Since deciding what is the best regulatory solution to complex problem is a different type of decision, cost-benefit analysis cannot be used in the same way in 'legislative' IAs. For example the added value of aggregated numbers for the costs and the benefits is less than clear. Political decision-makers want to know where the costs and benefits fall and are therefore better served by an overview of trade-offs. Although a cost-benefit approach does not necessarily involve monetisation, the Commission prefers to speak of 'positive and negative impacts' rather than 'costs and benefits' apparently in order to avoid misguided expectations that cost-benefit *analysis* is the method of choice in the Commission IA system.

Cost-effectiveness is sometimes proposed as an alternative for cost-benefit analysis, but it is not comparable as an analytical method: it is suitable only for minimising the costs of reaching certain pre-defined goals. Effectiveness is defined in the EU's Financial Regulation as "attaining the specific objectives set and achieving the intended results".[50] Cost-effectiveness is attaining set objectives at the lowest cost.

A methodology popular with those who feel that cost-benefit analysis is 'projecting the values of the analysis onto the regulatory choice'[51] and also suggested in the IA Guidelines is multi-criteria analysis. Multi-criteria analysis shows how different criteria lead to different formulations of the problem; it is based on a matrix which shows how different options perform in relation

48 *Ibid*., pp. 43-44.
49 See Annex 13, p. 42.
50 Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002, OJ L 248/1).
51 Claudio Radaelli at the DBR training course on IA in Exeter in July 2006.

to different criteria (efficiency, environmental protection, social preferences). The problem afterwards is always the same: how does one weigh the criteria? Although the popularity of this 'method' is understandable (for the same reasons that the 'highlighting trade-offs model is popular, see II.3.4) two drawbacks should be noted: a) it is a method for comparing different options, it is not a method for measuring impacts as such and b) it still involves explicit valuation, which can have the effect of heightening conflict in the decision-making process.[52]

The relative lack of agreement about objectives in EU lawmaking (see II.1.4) makes it necessary to present these techniques for assessing and comparing impacts on an equal basis in the Guidelines, but this will not make the contention disappear.

III.2.5 Comparison of options: identifying a preferred policy option?

The last analytical step involves that 'in the light of the impact analysis', the options are compared to see if it is possible to rank them and identify a 'preferred' option. No further guidance is provided as to which criteria should be used for this ranking. Here the tension between the 'justifying' function of IA and its 'challenging' function play out in full. The issue of whether or not the IA should contain a 'preferred policy option' at the end is so important for the functioning of IA in the legislative process that the following text from the IA Guidelines merits full quotation:

> The impact assessment process will not necessarily generate clear-cut conclusions or recommendations regarding the final policy choice. Moreover, that final choice is always left to the College of Commissioners. For that reason it will not always be possible for the IA report to conclude that one option is better than any of the others. In these cases it will be possible and desirable to rank the options according to various criteria, and to different rankings based on the various selection criterions.
>
> However, as an important aid to decision-making, the results and the alternative options considered – in all cases – need to be presented in a transparent and understandable way to provide the basis for a political discussion on the relative advantages and disadvantages of the relevant options. This allows political decision-makers to examine the trade-offs between affected groups and/or between the impacts on the social, economic and environmental dimensions. It also allows the design of any proposal to be improved so as to help minimise trade-offs, to identify accompanying measures aimed at mitigating any negative effects, and to maximise the opportunities for a 'win-win' outcome. Once the political decision has been

52 C.f. Sunstein's argument on 'incompletely theorised agreements'. C.R. Sunstein, *Legal Reasoning and Political Conflict* (Oxford, Oxford University Press, 1996).

> made, its justification should be given in the Explanatory Memorandum. In addition, where possible, the final choice should also be set out in the IA report, as long as this does not amount to suppressing the presentation of alternative options and their rankings.[53]

Identification of a preferred policy option as part of the impact can undermine its capacity to present all policy options in an objective manner. Thus, not forcing a preferred policy option can diminish the risk of window-dressing. Refraining from indicating a preferred policy option, however, poses an institutional risk. As '[e]ach proposal for a legal act constitutes a commitment on the part of the Commission'[54] there is a risk that leaving the IA open-ended by simply listing the trade-offs associated with each policy option will be interpreted by other actors as a lack of commitment and an open invitation to exchange the Commission proposal for one of the other options.

III.3 Rules on procedure

III.3.1 Scope of application

The scope of application of the IA requirement is not fixed in the formal IA framework but is for the Commission to decide. For the pilot phase in 2002 and 2003 a number of proposals was especially selected. The 2002 Communication on Impact Assessment also mentions certain categories of documents as 'normally exempted' from the IA procedure:

> [P]eriodic 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. The latter category includes implementing decisions, statutory decisions, technical updates, including adaptations to technical progress, competition decisions or acts which scope is limited to the internal sphere of the Commission.[55]

In 2004, the first year of full implementation for the new impact assessment procedure, a number of proposals were identified in the initial APS list of proposals for extended impact assessment in 2004. Most of these were confirmed and several were added to produce the final list of proposals selected for extended impact assessment in the Work Programme. In the Legislative and Work Programme 2004 the criteria for deciding which proposals should undergo an extended impact assessment were set out:

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53 COM(2003) 770 final, p. 6.
54 COM(2001) 726, p. 6.
55 COM(2002) 276 final.

- Whether the proposal will result in substantial economic, environmental and/or social impacts on a specific sector or several sectors;
- Whether the proposal will have a significant impact on major interested parties;
- Whether the proposal represents a major policy reform in one or several sectors.[56]

Although it remains a prerogative of the Commission to determine which proposals are subject to an IA, for both 2005 and 2006 the Commission decided to generalise the scope of application. Thus for these years a formal IA is required for all items on the Work Programme, plus possibly some extra proposals, to be decided on an ad hoc basis. The exceptions for Green Papers and proposals subject to consultation with the social partners are maintained though. The logic behind this is that Green Papers are effectively a consultation documents and when the social partners have the right to propose an option IA would interfere with that right.[57] When the commitment to carry out IAs for all legislative and policy-defining proposals contained in the Work Programme for 2006 was announced in that same Work Programme it was added that:

> [IA] may in certain cases lead to a decision to pursue the objectives in a different way, or not to proceed. In addition, impact assessments conducted during 2006 will prepare the 2007 programme.[58]

For 2007 the wording used for defining the scope of application was slightly different:

> [A]ll items identified as 'strategic initiatives' or 'priority initiatives' will be subject to impact assessment, with Green Papers, Social Dialogue measures, 'convergence-type' reports, and transposition of international agreements normally being exempted from this requirement.[59]

The 2007 Work Programme added that IA may also be carried out for items which do not feature in the Work Programme and – anticipating the establishment of the Impact Assessment Board – that the 'modalities for selection of these additional items will be 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'.[60] The one-on-one relation between the scope of application of the IA regime and the CLPW has one drawback: it gives DGs an incentive not to include an item in the catalogue. But DGs can

56 COM(2003) 645 final.
57 SEC(2005) 791, p. 6.
58 COM(2005) 531 final, p. 11.
59 COM(2006) 629 final.
60 *Ibid*., pp. 4-5.

also decide to carry out 'voluntary' IAs on items outside CLWP. DG Internal Market for example carries out IAs on a) all legislative proposals that are on the DG's Work Programme and b) any other proposal (including non-legislative items and Comitology measures) that is likely to have significant political, socio-economic or other major impacts.[61] Similarly DG Health and Consumer Protection's own version of a preliminary IA, the 'Scoping Paper' may lead to non-CLWP items to be subjected to an IA. For the issue of impact assessments of proposals adopted under the Comitology procedure see V.5.1.

III.3.2 A time to consult and a time to proceed…

Consultation processes in the Commission are regulated by the 'Minimum standards for consultation',[62] with the main rules reiterated in the IA Guidelines.[63] According to the Minimum Standards some participants in the consultation on the new consultation standards proposed that they 'should be separated from the Commission's approach to extended impact assessments'. This idea has not been taken up by the Commission since one of the main points of the reforms was to integrate assessment and consultation more. Both the Minimum Standards and the IA framework are governed by 'the overriding principle of proportionality'. Besides, 'the Commission has to assess its consultation needs on a case-by-case basis in line with its right of initiative'. Yet there are limits to how far integration of consultation and IA can go:

> [T]he Commission must emphasise that consultation can never be an open-ended or permanent process. In other words, there is a time to consult and there is a time to proceed with the internal decision-making and the final decision adopted by the Commission.[64]

It is important to distinguish stakeholder[65] consultation from data collection. The purposes and the rules differ. There is a separate guidance document on the collection and use of expertise.[66] Things can become blurred easily when experts are consulted: is this done for the sake of collecting objective data or is it rather to ask for their opinion? But also outside this category of consultees it is not always easy to tell consultation apart from data collection. Quite often it will be necessary to rely on numbers calculated by the industry, because

61 The Evaluation Partnership (TEP) (2007), p. 32.
62 COM(2002) 704 final.
63 SEC(2005) 791, pp. 9-12.
64 COM(2002) 704 final, p. 11.
65 The term 'stakeholder' can be confusing. It is often used to refer to lobbies, but the term covers any person, group or organization that could come out of the regulatory process as a winner or a loser.
66 COM(2002) 713 final.

the Commission has no means to calculate these numbers itself, or does not have access to all the information needed in order to arrive at the numbers. No explicit guidance is given on how to deal with this situation but one solution is to adopt an 'auditor's approach' to numbers presented by powerful stakeholders.

Consultation will never be a perfect process. In a pluralistic model in which the consultees are not pre-selected, it will often be easier for powerful organizations to get access to the process because they have the resources to monitor which consultations are going on and to prepare responses to those consultations relevant to the interests they represent (see V.6.2 and VI.1.2).

III.3.3 IA as part of the planning cycle

> [IA] will constitute a means of selecting, during the work programming phase, *those initiatives which are really necessary*.[67]

The Commission prepares its proposals through the annual Strategic Planning and Programming (SPP) cycle. In order to fulfil its role of facilitating internal decision-making IA must be integrated in this cycle.[68]

As of 2005, the actual, formal impact assessment is preceded by a Roadmap, which gives a first indication of the main areas to be assessed and the planning of impact assessment properly speaking.[69] This Roadmap, which in effect is a 'mini-IA', is first prepared in the run up to the Annual Policy Strategy in which it is included and then updated for publication together with the Work Programme. The explicit purpose of publication at this time is that external stakeholders can anticipate the timing of the IA work and prepare for a possible input from their side. When the Work Programme is being fixed there has already been a moment of political choice as to what sort of proposal is going to be prepared in a given year. Yet on the impact assessment front, all there is by that stage is a Roadmap, consisting of a prediction for further IA work and a rough estimation of the most important impacts. This order of affairs provides an incentive for the IA to serve most and for all as a justificatory document, along the lines of the reason-giving model (see II.3.2). If one wants to facilitate the use of the full IA as a preparatory information document, the IA work should be concluded before a certain item can be included in the Work Programme. This, however, would overhaul the legislative cycle considerably.

The IA is also discussed in an Inter-Service Steering Group. The Roadmap indicates whether an Inter-Service Steering Group will be established and must

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67 COM(2002) 275 final, pp. 3-4.

68 W.J.M. Voermans and D. van Berkel, 'Beter wetgeven in Europa: het nieuwe Interinstitutioneel Akkoord Beter wetgeven 2003' [2005] (3) *Regelmaat*, 89-94.

69 COM(2003) 770 final, p. 3.

give reasons if this is not the case. Preliminary reports imply that IA could facilitate inter-service cooperation.[70] Finally it should be mentioned that the Group of Commissioners on Competitiveness (a body, created by President Barroso at the beginning of the term of his Commission) can screen an IA at the request of the Commission President, although it is emphasized that the final decision on the proposal, including the IA always lies with the College of Commissioners.

III.3.4 The IA document

The impact assessment will normally be conducted by the desk officer(s) responsible for the proposal, because of the integration of the IA and the proposal. Contracting out of elements of the IA is allowed, provided that if these involve important parts of the impact assessment, the terms of reference state that the outside consultant has to take into account the analytical steps set in Part III of the IA Guidelines.[71]

The results of the IA process are published in an 'IA report'. This report has the status of Commission staff working paper (SEC document), so it does not reflect the opinion of the Commission as such. However, the fact that the IA report gets published together with the proposal does in the very least suggest a link. To clarify and formalise this link the idea that someone in the Commission should be responsible for putting a 'rubber-stamp' on impact assessments – reminiscent of the British ministerial declaration – has been put forward by Horst Reichenbach, director-general of DG Enterprise at that time, at a conference, but has not been followed up on.[72]

The Guidelines mention an indicated maximum length for the IA report of 30 pages. The TEP evaluation has concluded that the average length of an IA report is about 31 pages.[73] However, there are quite a few lengthy IA reports (see VI.2), with some observers voicing the impression that this is linked to the strong limits of the number of pages that the rules on translation impose on other documents such as the proposal itself and the explanatory memorandum.[74] The visibility of the IA report is reduced by a few very simple practical obstacles. First of all, not everyone who could potentially be interested in reading one or more Commission IAs will know how to find their way to the Secretariat-General's website, where all IA reports are listed. Although most DGs also publish their IAs on their own websites, usually on the thematic pages

70 European Policy Forum, 'Reducing the Regulatory Burden: the Arrival of Meaningful Regulatory Impact Analysis', City Research Series (London, 2004), p. 27.
71 SEC(2005) 791, p. 13.
72 EuropeanVoice.com, 'Enterprise chief demands more impact assessments', 7 April 2005.
73 The Evaluation Partnership, 'Evaluation of the Commission's Impact Assessment System. Annexes to the Final report (methodology and survey results)' (Brussels, 2007), p. 34.
74 Interview Commission official C; Interview national official B.

devoted to a certain policy area, this is by no means standard practice, nor is it recommended in the IA Guidelines. Another such obstacle is that although the IA report is included in the 'procedure file' in various official websites that follow the legislative process, things are not made easy for the user. In the Legislative Observatory[75] the link to the SEC document does not work – at least not in the cases checked for the purposes of this research project. The PreLex website[76] links to the IA report, but it is an html-version if the IA report only and at no point is it made clear that this document is an impact assessment. A similar vague label is in use by the Legislative Observatory which speaks of a 'document annexed to the procedure'.

An interesting question is what happens to impact assessment that never materialise into proposals (in a sense the most successful ones). The Commission has said that it would publish these on the Secretariat-General's website as well. However so far this has not happened, leading the European Parliament to

> [urge] the Commission to specify the stage reached by impact assessments which have not yet been published, making it clear whether those assessments are still pending or have been withdrawn, postponed or restarted on different grounds, etc., and to consult interested parties on those still pending.[77]

III.4 QUALITY CONTROL

III.4.1 The debate on external review

The creation of 'a body of "guardians of the rules" that could perhaps take the shape of a "European Conseil d'Etat"' is an old idea, first suggested by the French Conseil d'Etat,[78] and later repeated in the Koopmans Report (a report commissioned by the Dutch Presidency in 1996, see II.1).[79] Before discussing how the Commission's internal quality control of IA is organized, it is necessary to say a few words on the debate on external review as this issue is at the core of the debate on the future development of the EU IA system and can be seen as the driving force behind the decision to establish the Impact Assessment Board.

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75 Http://www.europarl.europa.eu/oeil/index.jsp?language=en (last accessed 15 July 2007).
76 Http://ec.europa.eu/prelex/apcnet.cfm?CL=en (last accessed 15 July 2007).
77 EP Lévai report on Better Regulation (2007), para. 14.
78 C.M. Radaelli, 'Steering the Community Regulatory System: the Challenges Ahead' (1999) 77 *Public Administration*, 860.
79 Koopmans report (1995).

External review by independent experts is seen by many, but most prominently by American experts, as an essential quality requirement.[80] Think tanks and lobby groups have joined in the discussion, usually arguing in favour of such review.[81] The European Parliament has also repeatedly expressed a preference for some kind of independent review on a structural basis. In the explanatory statement of his report MEP Doorn pleads in favour of an independent institution that can monitor 'the implementation of an impact assessment' which would allegedly prevent impact assessment from being 'turned into an instrument for opposing undesired legislation in an undemocratic manner'.[82] In his subsequent reports on Better Lawmaking Doorn repeats this request, emphasizing that it is essentially that the review is carried out by an *external* expert panel.[83] The idea that the IA procedure should undergo a mandatory peer review process is repeated in the McCarthy report, a more recent report on Better Regulation focussing on internal market legislation.[84] The argument can be summarised as follows: the Commission is a stakeholder in the process and therefore by definition cannot be trusted to provide an objective analysis. Possible counterarguments are that it is too early in the development of the IA procedure for the addition of a review mechanism, that it would only create extra problems ('who reviews the reviewers?') and that transparency is a sufficient control mechanism. The strongest argument against such an agency, especially one with sanctioning powers, is probably that many difficulties would arise from positioning such an institution within the institutional balance of the three co-legislators.[85]

III.4.2 Internal 'checks and balances'

The internal checks and balances for ensuring quality of Commission IA was not subject to clear institutional design from the very beginning. This section discusses how the growing role of the Secretariat-General in this regard has developed. It also gives a preliminary analysis of the recently established

80 R.W. Hahn and R.E. Litan, 'Counting Regulatory Benefits and Costs: Lessons for the US and Europe', AEI-Brooking Joint Center for Regulatory Studies (Washington DC, 2004).

81 The European Policy Forum proposes the following options: strengthening the oversight capacity of Secretariat-General, a new unit reporting to Commission President, the Court of Auditors, a new independent agency and private informal review. G. Mather and F. Vibert, 'Evaluating Better Regulation: Building the System', City Research Series, European Policy Forum (London, 2006).

82 EP Doorn report (2004).

83 EP Doorn report (2007); EP Doorn report (2007). See also EP Lévai report on Better Regulation (2007).

84 EP McCarthy report (2006).

85 Bevis Clarke-Smith of the Legal Service of the Commission at the BR symposium, O. Kwast and F. Simon, 'Minutes of the Symposium on 'Better Regulation' in the European Union' [2005] *Sociaal-economische wetgeving SEW: tijdschrift voor Europees en economisch recht*, 254.

Impact Assessment Board (IAB). Apart from these general mechanisms, some DGs have their own rules: in DG Enterprise for instance, before submitting a proposal to the cabinet, a policy unit has to ask the special IA unit for advice.

The Secretariat-General

The Secretariat-General of the European Commission has a key role in enforcing some of the procedural rules discussed in the previous section. One example is the monitoring of DGs so that they do not resort to trying to leave items outside of the CLWP in order to avoid doing an IA. The Secretariat-General has to be included in every Inter-Service Steering Group, allowing it to follow the IA process. Through its right to give a suspended opinion in the Inter-Service Consultation (ISC), the Secretariat-General can also try to safeguard the substantive quality of the IAs. The TEP evaluation reports that not many suspended opinions have been issued as the Secretariat-General prefers a proactive approach, but also that the number has apparently risen since the establishment of the IAB.[86] Other reports confirm this overall picture: it is not necessarily the Secretariat-General issuing IA-related suspended opinions in the ISC. Several DGs – notably but not exclusively DG Enterprise – have issued negative opinions because of insufficient impact assessments on occasion.[87]

Impact Assessment Board

After President Barroso acknowledged the need to respond to the varying quality of Commission IAs at the European Parliament plenary discussion on Better Regulation on 4 April 2006, the Commission committed to establishing a quality control body on 14 November 2006.[88] Subsequently a note by the President officially established the Impact Assessment Board (IAB). The Board consists of five high-level officials (Director level) who act independently of their own Directorates-General and other policy making departments. The Board currently consists of the Deputy Secretary-General who acts as chair and of the Directors-General of the following DGs: DG Enterprise, DG Employment, Social Affairs and Equal Opportunities, DG Economic and Financial Affairs and DG Environment.[89] These DGs were chosen because they represent all three pillars of IA and because they have considerable experience in IA, having been actively involved in the pilot phase and the IA Working Group.

86 The Evaluation Partnership (TEP) (2007), p. 60.
87 Informal communication EU official.
88 COM(2006) 689.
89 This composition is entrenched in the current mandate of the IAB, see http://ec.europa.eu/governance/impact/docs/key_docs/iab_mandate_annex_sec_2006_1457_3.pdf (last accessed 15 July 2007).

The IAB works under the direct authority of the President and reports directly to him. The Board members are supported by a secretariat consisting of officials from the Secretariat-General. Both internal and external expertise may be used on a case-by-case basis. The term of office of the IAB members is two years with the possibility of extension.

Rather than a stringent regulatory overview body along the lines of the American Office of Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB), the IAB is part of an internal system of checks and balances. It operates alongside internal Commission quality control mechanisms such as the support units in the DG, the presence of the Secretariat-General in Inter-Service Steering Groups (see previous section), the informal economists' IA network which meets once a month over lunch, the IA working group which was continued after the 2005 stock-taking process and the high-level group of national regulatory experts whose mandate covers only general policy advice. The task of the IAB is to scrutinise the quality of individual Commission IAs. The IAB will 'provide widespread quality advice and control whilst ensuring that the responsibility for preparing assessments and the relevant proposals remains with the relevant departments and Commissioners' and 'contribute to ensure that impact assessments are of high quality, that they examine different policy options and that they can be used throughout the legislative process'.[90] It is envisaged that although micro-level quality control will be the initial focus of the board, its activities will gradually broaden to 'advice on methodology and on the approach at the early stages of impact assessment preparation'.[91] In the medium term the Commission expects the IAB to 'offer advice and support in developing a culture of impact assessment inside the Commission' and 'to develop into a centre of excellence'.[92]

The competences of the IAB are no straightforward matter and had to be drawn up whilst carefully navigating between various constitutional principles and existing internal procedural rules. In fact, even the composition of the Board was a sensitive issue, raising concerns in the Commission services that the IAB, no matter how carefully the represented DGs were selected and no matter how many times it is emphasized that the Board members act in personal capacity, cannot commit their DGs concerning individual IAs and may not receive instructions from their DGs.[93] The possibility of giving the IAB the power to issue 'return letters' – a competence many stakeholders in favour of strong review of IA would have liked to see included – was thwarted because it would breach the principle of collegiality (Article 217 TEC) since

90 COM(2006) 689, p. 8.

91 Http://ec.europa.eu/governance/better_regulation/impact_en.htm#_quality (last accessed 15 July 2007).

92 COM(2006) 689, p. 8.

93 See the Rules of procedure of the Impact Assessment Board http://ec.europa.eu/governance/impact/docs/key_docs/iab_rules_of_procedure_final.pdf (last accessed 15 July 2007).

the possibility of delegation to one commissioner only is limited to administrative acts.[94] Awarding the IAB such a competence would probably have caused quite an uproar within the Commission services when there was already a risk that services would feel that the President pushed through the IAB too quickly and at the expense of their traditional discretionary powers. As matters currently stand the IAB has no veto power but it is entitled to ask for resubmission of draft IAs. Since the IAB gets involved even before initiatives reach the step of Inter-Service Consultation (DGs are required to submit their draft IAs one month before the launch of the ISC) there is always a risk that the line between quality control and control over substance will become blurred. The Secretariat-General, represented on the Board in the person of the Deputy Secretary-General, has a role in ensuring that the Board's advisory powers do not slip into a *de facto* veto power. The IAB also has the competence to send DGs so-called 'prompt letters', asking them to carry out IAs on items falling outside the current obligatory scope of items included in the CLWP.

After initial hesitation, the Commission has decided to publish all IAB opinions,[95] but only after the proposal and the IA have been published in order to avoid the IAB opinions being seen as 'previews' of the real IAs, opening up the policy-making process at a point in the process when space for discretionary decision-making is most needed. The first 11 IAB opinions have been published on the Secretariat-General's impact assessment website. An important detail – also mentioned on the IA website – is that the IAB opinions may refer to IA documents which differ from the one published, as the Board works on the basis of draft impact assessments. This means that it will be hard to fully assess the way the IAB works as the draft impact assessments are not public documents. Also, no list with screening criteria used by the Board has been published. Obviously the Board will look at the Guidelines, but these are not necessarily suitable for quality control and some kind of more concise set of criteria will inevitably emerge, if it has not been explicitly created. This list will represent the standards for IA more closely than the Guidelines and as more IAB opinions get published they will probably be – explicitly or implicitly – deductible from the opinions.

As to the issue of how we can find out whether or not the recommendations from the opinions have been taken on board in the final IA, a sample from the limited set of cases in which an opinion has been published up to now shows a varied practice. The three IAs of the 'Regulation on administrative

94 A. Alemanno, 'The Legal Implications of the EU Initiative on Better Regulation: A Trojan Horse within the Commission's Walls?', paper delivered to the 1st Advanced Colloquium on Better Regulation at the Centre for Regulatory Governance, University of Exeter, 25-26 January 2007 (Exeter, 2007), p. 6.

95 Regulation 2001/1049 would probably have obliged the Commission to grant access to most of these opinions upon application by members of the public anyway.

burden reduction omnibus' do not mention the Board's opinion at all.[96] One IA (on the Renewed Market Access Strategy[97]) starts out with a statement that '[t]his document takes full account of the Opinion of the Impact Assessment Board' and a summary of the procedure before the Board, followed by a summary of how the opinion has been taken into account throughout the IA. The fifth IA, on the European Space Policy,[98] contains an appendix reiterating the main recommendations by the IAB and listing the amendments made to the IA in response to those. Of these three options the latter could well develop into 'best practice'. Giving no clue whatsoever as to in what way the IAB recommendations have been taken into account is confusing (especially when it takes only one mouse click to discover that the IAB did in fact have substantial criticism!) and it would be much better to include a brief statement, rather than leaving it to the research community to uncover the traces of the IAB's influence. The second approach (including such a statement in the beginning) could work, but could also distract from the substance of the IA itself. The third option seems a good way of dealing with yet another procedural problem that IA causes, a phenomenon that can be seen as circumstantial evidence for the hypothesis that IA represents a clean break with 'policy-making as usual' in the Commission.

There are great expectations for the IAB. As a Commission press release put it:

> The system for impact assessment of all major new proposals for legislation will be beefed up to ensure quality and objectivity through the establishment of an Impact Assessment Board.[99]

The establishment of the Board was also well-received in the Council:

> Substantial progress has been achieved in the area of better legislation. The evaluation of the Commission's impact assessment system will help identify further improvements, including through the enhanced consideration of aspects relevant for external competitiveness as part of the economic impact pillar. With a view to further improving the quality of the impact assessment system, the European Council sees the establishment of an "Impact Assessment Board" by the Commission as an important step.[100]

96 HACCP – Food hygiene (SEC(2007) 302), Company Law – Mergers (SEC(2007) 300), Regulation 11 Transport (SEC(2007) 303).

97 SEC(2007) 452/3.

98 SEC(2007)505.

99 European Commission, press release, 'Proposed cuts of 25 % in red tape to lead to increase in EU GDP of 1.5%', IP/06/1562, 14 November 2006. http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/1562&format=HTML&aged=0&language=EN&guiLanguage=en (last accessed 4 March 2007).

100 Council conclusions of March 2007, para. 23.

The European Parliament has also welcomed the step of establishing the IAB, but has expressed disappointment that the Board is not an 'external expert panel' and has already called for an evaluation of the functioning of the Board before the end of 2008.[101] In addition, the report by rapporteurs Katalin Lévai also asks that 'Parliament be informed periodically of the decisions adopted by the Impact Assessment Board under the supervision of the President of the Commission, with a view to ensuring transparent dialogue between the two institutions'.[102]

It is entirely feasible that over time the IAB will develop its own 'case law', including new or more concrete procedural and substantive standards that will be consulted by officials faced with a new IA process. For now the more limited conclusion seems warranted that the establishment of the Board represents the next step in the progressive formalisation of the IA procedure, forcing Commission officials involved in IA to be more explicit about choices made in IAs.

III.4.3 Evaluation of the IA system

Self-assessment

The Commission has engaged in informal self-assessment with regard to its IA regime several times now (the stock-taking exercise after the pilot phase was already mentioned, see III.1.3). Most of the statements in this context voice the impression that some sort of culture change is ongoing. Back in 2003 the Commission came to the following assessment of the outside impression of its IA system:

> In its current state, impact analysis is seen by its critics as sandwiched between making qualitative assessments that are very subjective and trying to make quantitative assessments that may be very unreliable.[103]

But it went on to state that:

> In qualitative terms, the direct and indirect consequences of adopting such a new procedure have been positive overall: it has contributed significantly to improving transparency, strengthening the analytical content of proposals, promoting coordination between departments and dialogue with those sectors more particularly concerned by the Commission's initiatives.[104]

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101 EP Doorn report (2007), para. 22.
102 EP Lévai report on Better Regulation (2007), para. 7.
103 COM(2003) 770 final, p. 4.
104 *Ibid*., pp. 35-36, note 103.

Recently, a Commission official estimated that 'IA has a real influence, in the sense that it causes the final proposal to be different compared to early ideas on how to regulate a certain issue, more than half of the time'.[105] This carefully positive impression that the legislative culture within the Commission is developing in the right direction is exploited unscrupulously at the political level:

> I think we can actually be very proud of the fact that the impact assessment developed by the Commission has an extremely good reputation internationally, and, while I do not believe that you will find anything better anywhere in the public sphere, there is still room for improvement, and that is something we can work on together.[106]

Of course the above is just one, subjective impression. One indicator for measuring change could be whether IA is stopping projects. The Commission committed itself to publishing IAs that never led to a proposal, but so far this has not happened. There is anecdotal evidence that IA is postponing proposals, for example because the IA shows that more detailed info is needed.

External evaluation

Apart from various informal academic reviews,[107] which almost all were made with reference to the pilot phase (albeit not always explicitly so), an external evaluation of the Commission IA system was commissioned in 2006, in response to stakeholder pressures. The call for tender was won by The Evaluation Partnership (TEP), a London-based consortium and the final report was published in late June 2007.[108] From the multitude of goals of the IA system (see I.1 and III.1) the consultants have isolated three main objectives around which their evaluation is centred:

1. Improve the quality of Commission proposals, in particular by
   - Facilitating a more systematic, coherent, analytical, open, and evidence-based approach to policy design;
   - Providing a thorough, balanced and comprehensive analysis of likely social, economic and environmental impacts.
2. Provide an effective aid to decision-making, in particular by
   - Providing policy makers with relevant and comprehensive information on the rationale behind proposed interventions, and their likely impacts;

105 Informal communication Commission official.
106 Verheugen on 27 September 2005 in a plenary debate in the European Parliament.
107 Lee and Kirkpatrick (2004); Renda (2006); Vibert (2004); Vibert (2005); Wilkinson et al. (2004).
108 The report and annexes are available at http://ec.europa.eu/governance/impact/key_en.htm (last accessed 20 July 2007).

- Enabling policy makers to assess trade-offs and compare different scenarios when deciding on a specific course of action.

3. Serve as a valuable communication tool, in particular by
   - Fostering internal communication and ensuring early and effective co-ordination within the Commission;
   - Enhancing external communication by making the policy development process more open and transparent to external stakeholders.[109]

Almost perfectly in line with the impact assessment template, the evaluation presents 'options for change' at the end of the report, each with their respective advantages and disadvantages listed. Finally it should be noted that the annexes to the final report contain a wealth of empirical information on IAs that could also be used for different purposes by other researchers.[110]

III.5 IA IN RELATION TO OTHER TOOLS AND PROGRAMMES

III.5.1 Links with other Better Regulation projects

IA and the screening of pending proposals[111]

When the Commission announced its intention to withdraw 68 legislative proposals as the result of a screening exercise of all proposals pending before the Council and Parliament[112] prior to 1 January 2004, one of the criteria listed was whether the proposal had undergone an impact assessment. The Commission press release also stated the reasons for withdrawal for each proposal. The quoted reason why the proposal on 'Weekend bans for trucks'[113] had been withdrawn was that

> [t]his proposal has never been impact assessed. The controversial reception by the other institutions and some MS as well as the current blockage at the Council

109 The Evaluation Partnership (TEP) (2007), p. 3.

110 The Evaluation Partnership, 'Evaluation of the Commission's Impact Assessment System. Annexes to the Final report (case study reports)', SG-02/2006 (Brussels, 2007); The Evaluation Partnership (TEP) – Annexes methodology and survey results (2007); The Evaluation Partnership (TEP) – Annexes quality assessment (2007).

111 COM(2005) 98 final, p. 3.

112 Some MEPs feel that the Commission should have consulted the European Parliament when drawing up the list. European Voice (2005).

113 COM 1998/0096 – 1998/115: Proposal for a Council Directive on a transparent system of harmonized rules for driving restrictions on heavy goods vehicles involved in international transport on designated roads.

(because of the links with the Eurovignette Directive) requires its withdrawal for a full re-assessment on the basis a proper impact analysis.[114]

Lack of impact assessment was quoted in the context of some other withdrawals as well. The Commission also announced that five proposals would be subjected to further economic impact analysis. A further ten proposals will be withdrawn in 2007 and the Commission will continue to regularly monitor pending legislation to make sure that it is relevant and up to date.[115]

IA and simplification

The simplification exercise is similar to IA in that it also aims to let European legislation be something more rational than the best possible political compromise. Those instances where competitiveness could be really helped by simplification, are often too politically controversial however to be achieved through such an exercise as simplification in the context of a Better Regulation action plan, which is after all presented as neutral. In other words: real simplification will always be controversial. In October 2005, the Commission published a Communication setting out new proposals to simplify existing legislation. It announced a three year rolling programme to repeal, codify, recast or modify 222 basic legislative regimes, covering around 1,400 legal acts. Additionally, it will adopt a new sectoral approach to simplification, beginning with reviews of the legislation affecting automotive vehicles, construction and waste. It should be noted that the kind of amendments made in these simplification programmes usually do not touch upon the content of the legislation (see II.1.1 and the BEST and SLIM initiatives).

IA and self-regulation and co-regulation

The promotion of self-regulation and co-regulation are important elements of the Inter-Institutional Agreement on Better Lawmaking, which sets out general principles to be respected when using these 'alternatives to regulation':

- Consistency with Community law
- Transparency (publicity of the self-regulatory agreements)
- Representativeness of the parties involved
- No referral to these mechanisms when fundamental rights or the uniform application of rules in all Member States are at stake

A survey on whether IA actually enhances the use of alternative instruments is beyond the scope of this thesis. Therefore this quotation from the Commissi-

114 MEMO/05/340, Better Regulation, http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/340&format=HTML&aged=0&language=EN&guiLanguage=fr (last accessed 27 March 2006).

115 COM(2006) 689, p. 9.

on's 'Strategic review of Better Regulation' which claims that it does, will have to suffice:

> Commission decisions on whether and how to proceed with an initiative are based on a thorough analysis of options. The option of no EU action together with alternatives to legally binding legislation (self- and co-regulation) is routinely examined. As a result, some planned measures have been significantly adjusted: impact assessments on biomass, the urban environment, and copyright in the online music sector led to the conclusion that binding measures were not necessary.[116]

IA and the measurement of administrative burdens

A development that has to be mentioned but will not be further explored in this thesis is the addition of administrative burden measurement as a special focus for Commission impact assessments. In 2004 the Competitiveness Council asked the Commission and the Member States to evaluate 'the cumulative impact of existing legislation on the competitiveness of industry and of specific industry sectors' and to develop 'a method for measuring administrative burden on business'. In November 2006 the Commission, following a number of pilot projects, announced its plans for a methodology to measure the administrative costs of new regulatory proposals and its intention to incorporate the methodology into impact assessments where appropriate. The administrative burden theme has been so dominant in the last year that a spokesman for Verheugen even saw reason to claim in an interview that '[t]he Better Regulation Program is *aimed at* cutting the administrative burden for the business world with about 25% by 2012.'[117] In a previous section the differences between various 'techniques' for impact assessment have already been highlighted (see III.2.4). The 'Standard Cost Model' (SCM), the technique generally used for measurement of administrative burdens (AB) is again completely different and belongs to an approach to Better Regulation that is a far cry from the one set out in the 2002 Action Plan. The SCM was originally developed for the existing stock of regulation not as a technique of ex-ante assessment. The approach it stems from is aimed at cutting financial burdens for specific groups (most often business) whilst leaving aside completely the benefits of regulation.[118] The 'special focus' on administrative burden only adds the confusion surrounding techniques to be used in EU IA and makes IAs unfit as a basis for balanced legislative decision-making.

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116 *Ibid*., p. 7.

117 Http://infoeuro.biz/id/9878/ (last accessed 4 January 2007). Emphasis AM.

118 A.C.M. Meuwese, 'How to measure regulatory impact?' in The Lisbon Scorecard VII. Will globalisation leave Europe stranded?, K. Barysch, S. Tilford, and A. Wanlin (eds), Centre for European Reform (London, 2007), pp. 71-72.

The Commission's efforts go down rather well with the European Parliament. In its 2007 round of reports on Better Regulation[119] the Parliament expresses its support for the burden reduction programme, whilst proposing that the Commission also carry out a study in order to 'develop a methodology to quantitatively chart and assess, in addition to the administrative burden, all other burdens relating to compliance'.[120] On top of that, the Doorn report also

> [e]mphasises that Parliament should not take into consideration any legislative proposals from the Commission that are not accompanied by an independently scrutinised impact assessment that includes an evaluation of the existence of any unnecessary administrative burden through the SCM.[121]

This is in line with an earlier adaptation by the Commission of administrative burden measurement methodology on the grounds that the Protocol on proportionality and subsidiarity required that not only the costs imposed on enterprises were assessed, but also those falling on public authorities, the voluntary sector and citizens obligations.[122]

III.5.2 Links with pre-legislative support tools

The European Commission meant the new impact assessment procedure to 'integrate, reinforce, streamline and replace'[123] all existing practices in the field of ex ante evaluation. Yet, a lot of pre-legislative support tools still exist in parallel with IA. This section compares impact assessment to some of these tools: the Explanatory Memorandum, ex ante evaluation, various specialised assessments, human rights screening and the precautionary principle. These 'tools' are of a varying status and nature and the dialectic tone chosen for the comparison (IA *versus* …) is not always as appropriate. Yet, it is a conscious choice to take potential tensions between IA and other tools as the starting point: interviews and analysis of – formal and informal –debates on Better Regulation have shown that confusion among users and addressees of these tools, as well as an element of competition, are real.

119 EP Lévai report on Better Regulation (2007); EP Doorn report (2007); EP Medina Ortega report on the use of 'soft law' (2007). These reports were discussed in the European Parliament plenary on 3 September 2007 in Strasbourg.
120 EP Doorn report (2007), para. 26.
121 *Ibid.*, para. 21.
122 SEC (2005) 1329, p. 11.
123 COM(2002) 275 final.

IA versus Explanatory Memorandum

It is entirely possible that, when explaining the concept of IA to someone who is not familiar with it, the reaction is something along the lines of 'do you mean an explanatory memorandum'? Indeed in many continental legislative systems the role of IA – an Anglo-Saxon concept by origin – is fulfilled by explanatory memorandums, implicitly following the 'reason-giving' model (see II.3.2). The memorandum accompanying the legislative proposal is the document that contains information on the motivation to embark on the proposed course of action. However it often also contains some information on the effects of the proposed legislation – economic, environmental, social, budgetary or otherwise – that could be of interest to the legislator. In many of these systems the guidelines on legislative drafting prescribe in detail what the explanatory memorandum should contain and it often resembles IA-type requirements to a deceiving degree. It is also possible to argue that it is crucial for the emancipation of the tool that IA distinguishes itself from the explanatory memorandum.

Initially – in the run-up to the development of Better Regulation policy – the Working Group on Evaluation and Transparency already suggested that as part of a strategy for avoiding always being blamed for poor legislation the Commission should 'anticipate regulatory criticisms by extending its explanatory memorandum practice'.[124] Now that the IA system is more developed the idea is that information from the IA should feed into explanatory memorandum. In particular, the results of the subsidiarity analysis from the impact assessment will feature in the Explanatory Memorandum accompanying any legislative proposal, the format of which has been improved. Whereas both provide reasons for intervention, IA has more of a guiding function at the stage when the proposal is still being developed, whereas the explanatory memorandum is the tool meant for justification of the proposal. The European Commission has introduced a standardised format for drafting Explanatory Memorandums. When this electronic format is used it is easier to collect the relevant information need for, among other things, the reports on better lawmaking.

IA versus ex ante evaluation

A second pre-legislative support tool risking confusion and overlap with IA is ex ante evaluation. The Commission has gradually expanded its evaluation practices,[125] especially since the introduction of Strategic Programming and

124 EC Report on 'Evaluation and Transparency' (2001), p. 3.
125 For an overview see SEC(2000)1051.

Planning (see III.3.3).[126] The Working Group on Evaluation and Transparency provided the following definition of ex ante evaluation in their report:

> Its main purpose is not to pass a judgement on whether or not an initiative should be launched or not but rather to analyse how an initiative should be formulated and how it should be managed to ensure that it achieves stated objectives, and at what cost the desired impact can be achieved.[127]

This definition sounds conspicuously like a definition of IA, albeit one that is carried out in a later stage and is oriented towards cost-effectiveness rather than one allowing for multiple techniques. However, confusingly, the term 'ex ante evaluation' is mostly reserved for a requirement to assess the impacts on the budget solely, which was already in place when the IA system was established. Ex ante evaluations of all programmes and activities which entail significant spending in the Commission have really taken off with the implementation of Financial Regulation 1605/2002/EC of 1 January 2003. Article 28(1) of the same regulation extends the assessment obligation to legislative proposals 'which may have an impact on the budget'. There are some obvious overlaps as both tools engage in the prospective assessment of impacts as well as important differences. The scope of application is still different, but what used to be the main difference, the range of possible impacts covered, has been minimized by an amendment of the implementing regulation of the Financial Regulation. Article 21 on Evaluation has been amended by adding the following key steps:

> (d) the policy options available, including the risks associated with them;
> (e) the results and impacts expected, in particular economic, social and environmental impacts, and the indicators and evaluation arrangement needed to measure them;
> (f) the most appropriate method of implementation for the preferred option(s);
> (g) the internal coherence of the proposed programme or activity and its relations with other relevant instruments.[128]

This clarification does not completely solve the question how the two forms of evaluation relate to one another. The current rule is that whenever both an IA and an ex-ante evaluation are required the two should be combined. The IA Guidelines clearly indicate that wherever possible the ex ante evaluation should be integrated into the IA:

126 Http://ec.europa.eu/atwork/cycle/index_en.htm (last accessed 17 July 2007).
127 EC Report on 'Evaluation and Transparency' (2001), p. 8.
128 OJ L 227/3. Commission Regulation No 1248/2006 of 7 August 2006 amending Regulation No 2342/2002 laying down detailed rules for the implementation of Council Regulation No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities.

> As long as your impact assessment for a proposal having budgetary implications properly addresses all items listed in Article 21(1) of the Implementing Rules, it will be accepted as an ex-ante evaluation. Since these items are similar to the IA requirements in many ways, no 'extra' work is likely to be necessary. Particular attention will need to be paid to the cost-effectiveness of the various options reviewed.

In practical terms this could mean that a) evaluations of previous or similar programmes can be used as an input to the IA and b) the IA should pay particular attention to considerations of cost-effectiveness, after all the main concern of ex ante evaluation in the narrow sense as used by the Commission.

The TEP evaluation (see III.4.3) reported a 'genuine difference of viewpoint by informed actors in the Commission' on the subject. As an illustration one TEP interviewee reportedly said that IA is about 'how to write a law' and ex ante evaluation is about 'how to spend money', whereas another stated that it did not make sense to have both, and that 'ex-ante evaluation needs to be part of IA'.[129] The majority (51%) of the respondents in the survey TEP carried out said it was not clear to them where IAs and ex ante evaluations are overlapping, where they are complementary to each other, and where the demarcation line between the two is, with only 15% of respondents answering that it is sufficiently clear.[130] At the same time TEP reported no great problems in practice and recommended minor changes to the guidance documents, including specific guidance on the possibility of doing both processes in one.

IA versus specialised assessments

In a strange twist of bureaucratic fate, while attempts to streamline *integrated* impact assessment in the Commission were ongoing, several initiatives to put in place or further develop specialised assessment tools were taken, raising the question of how these should operate in relation to 'mainstream IA'.

The first and best-known example is 'Sustainability Impact Assessment' (SIA), in use by DG Trade and applicable to international trade negotiations only.[131] A further difference is that SIAs are conducted by independent external consultants, selected on the basis of an open call for tender, whereas IAs are done in-house as much as possible. The SIA handbook has been revised in March 2006 and this revision took into account the adoption of the new, general impact assessment system:

> In 2002 the Commission published a Communication on Impact Assessment (COM 2002 276) by which it introduced a comprehensive regulatory and assessment framework for all policy areas, including trade. Trade SIAs remain, however, the

129 The Evaluation Partnership (TEP) – Annexes case studies (2007), pp. 291-292.
130 The Evaluation Partnership (TEP) (2007), p. 40.
131 Http://ec.europa.eu/trade/issues/global/sia/index_en.htm (last accessed 15 July 2007).

> most sophisticated form of impact assessment used by the European Commission.[132]

The handbook now offers a clarification of the relationship between IA and SIA in the European Commission:

> [General] Impact Assessments take place primarily before a proposal is approved: they are a tool for evaluating *whether* the action should be taken. In the case of major trade agreements, the Commission undertakes this general Impact Assessment in-house and proposes a negotiation mandate for the Council's endorsement. The Council makes a final decision on the basis of both documents.[133]

For the sake of a 'smooth transition between the general Impact Assessment and the Trade Sustainability Impact Assessment the following procedure is recommended:

> *Process:* A consultation group made up of representatives of different European Commission departments should be set up to carry out the general Impact Assessment and should bear in mind the subsequent Trade SIA phase from the outset;
>
> *Substance:* general Impact Assessments should highlight the aspects on which external consultants carrying out subsequent Trade SIA work may wish to concentrate their research. The terms of reference for a Trade SIA should be drafted taking into account the Impact Assessment results and wider consultation with experts and stakeholders.[134]

Furthermore, a proliferation of smaller and even more specific assessments can be observed. The interservice Quality Support Group (iQSG) assesses development DG Development policies, focussing on overall quality and on the internal and external coherence of documents.[135] For DG Regional Policy the cost-benefit assessment of major projects that receive financial support under the Structural Funds or the Cohesion Fund, mandatory on the basis of Article 40(e) of Regulation 1083/2006, is a major issue.[136] Other suggestions made are a crime proofing test (a special check whether there are no loopholes in the legislation that can be abused by criminals) and a special test on land use. Often these initiatives develop without the involvement of the Secretariat-

132 SIA Handbook (2006), p. 7.
133 *Ibid*., p. 11.
134 *Ibid*.
135 Http://ec.europa.eu/development/How/Methodologies/Programming_en.cfm (last accessed 16 July 2007).
136 European Commission, DG Regional Policy, 'The New Programming Period 2007-2013. Guidance on the methodology of cost-benefit analysis, Working Document No. 4, 2006, available at http://ec.europa.eu/regional_policy/sources/docoffic/2007/working/wd4_cost_en.pdf (last accessed 17 July 2007).

General, making its task to ensure IA in the Commission is integrated an even more challenging one.

A similar debate on whether integrating specialised tests as much as possible into the general IA framework is best or rather keeping them separate so as not to overburden the procedure, has been conducted in the UK as part of the 2007 revision of the RIA template (now also called IA). The solution chosen is to distinguish results of any tests that impact on the cost-benefit analysis (to be included in the main evidence base) and those results which are not included (to be presented in annexes).[137]

IA versus 'human rights screening'

The idea that the executive can act as 'the guardian of legal values in the preparation of the Government's legislation'[138] has been expressed by Daintith and Page. It is important to stress though that impact assessment processes within the Commission for the most part are separate from legal checks on proposals, with no special involvement of the Legal Service beyond the possibility to comment in the Inter-Service Consultation, that every DG is entitled to.

The only exception concerns the pre-legislative scrutiny for compliance with the Charter of Fundamental Rights.[139] This 'human rights screening exercise' has been part of the range of single issue assessments ever since the Commission decided on 13 March 2001 that this would be obligatory for any proposal for legislation and any draft instrument to be adopted.[140] It was also decided that legislative proposals and draft instruments having a specific link with fundamental rights would carry a formal statement of compatibility. The Commission Communication on Compliance with the Charter of Fundamental Rights in Commission legislative proposals from 2005[141] links this obligation to IA, mentioning it as part of a 'methodology for systematic and rigorous monitoring' (the Communication's subtitle). The document clearly distinguishes between the respective roles in this strategy for 'impact assessment', 'which should include as full and precise a picture as possible of the different impacts on individual rights' and the explanatory memorandum

137 Race, Disability and Gender Impact Assessments are a statutory requirement for all relevant policies. UK Impact Assessment Guidance, 'Specific Impact Tests: what should be covered?', http://www.cabinetoffice.gov.uk/regulation/ria/ia_guidance/specific_impact_tests.asp (last accessed 16 July 2007). See also the new UK IA template (2007), http://www.cabinetoffice.gov.uk/regulation/documents/ia/template.pdf (last accessed 16 July 2007).

138 T. Daintith and A. Page, *The Executive in the Constitution, structure, autonomy and internal control* (Oxford, Oxford University Press, 1999), p. 254.

139 OJ C 364/1, 18 December 2000. The Charter was solemnly proclaimed by the Presidents of the European Parliament, the Council and the Commission on 7 December 2000.

140 SEC(2001) 380/3.

141 COM(2005) 172.

which deals with the legal basis for compliance with fundamental rights. The Communication elaborates:

> The impact assessment provides the Commission, right from the start of the drafting process, with a complete picture of the various impacts which the process can have on the individuals and groups whose rights may be involved, depending on the different options envisaged. On the other hand, an impact assessment cannot be used to contain the legal scrutiny, i.e. the legal definition of the impacts identified in the light of the provisions of the Charter and the European Convention on Human Rights, and the case-law. The legal scrutiny calls for specific expertise and should concern an advanced draft proposal.[142]

Thus, impact assessment is expected to prepare the ground for the definitive legal verification of compliance with the Charter.

The Communication also justifies the decision not to create a separate category for fundamental rights impacts in the revised guidelines or a sub-heading within the section on social impacts, but rather to integrate these impacts into the three existing categories, namely economic, social and environmental impacts. The reason for this approach is that the fundamental rights of the Charter are diverse and cut across all sectors. This choice received criticism from legal academics[143] and also came under attack from the rapporteur in the European Parliament, who wrote that he vigorously opposed the Commission's intention at the time. He contends that the reason giving by the Commission for not giving fundamental rights a special treatment is 'precisely an argument in favour of creating a separate category, which would, in particular, avoid the risk of certain rights that do not specifically come under one of the three abovementioned headings being overlooked'. Furthermore he argues that '[t]he creation of a separate category would also assist the 'visibility' of the Commission's efforts in relation to compliance with fundamental rights, which is one of the Commission's declared objectives.'[144]

The Guidelines approach may be flexible but the question whether the Commission's IA system really fits all type of proposals has been repeatedly asked.[145] Conveniently interpreting the Commission IA framework in a literal way, but also addressing a real problem is the following quote from an annex to an IA on changes to human rights regulations:

> According to the Commission Communication on Impact Assessment, the type of impact, which a (policy) proposal has on particular groups, sectors or regions, should be expressed as far as possible in economic, social and environmental terms.

142 *Ibid*., pp. 3-4.
143 H. Toner, 'Impact Assessments and Fundamental Rights Protection in EU Law' (2006) 31 *European Law Review,* 316-341.
144 EP Voggenhuber report (2006), p. 3.
145 Toner (2006).

> The proposals for which this impact assessment is undertaken, though, do not consist in policy proposals. They are rather of a technical legal nature as has been amply explained under points 1, 2 and 3 above. It appears nevertheless meaningful to undertake as far as possible a stocktaking of discerned past impacts of the policy underlying Council Regulations (EC) No 975/1999 and 976/1999. This will then also provide a perspective for expectations of impacts in the period of extension of the validity of Council Regulations (EC) No 975/1999 and 976/1999 from 2005 to 2006.[146]

IA versus the precautionary principle

An internationally agreed understanding of the foundation underlying the precautionary principle is that 'where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation'.[147] However, this basic assumption is phrased in a negative way and does not offer any clear-cut guidance as to when positive action is required. Throughout its existence '[v]arious parties relate to the 'precautionary principle' with various understandings, demands and hopes'.[148] But it is fair to say that the principle enjoys greater popularity in Europe than anywhere else in the world.[149] Even so, the precautionary principle has a very different stature within the European Commission than IA: although it has a firmer legal basis it has less 'teeth', for lack of implementing mechanisms.

Article 174 of the TEC contains the a requirement to apply the precautionary principle: EU lawmaking in the environmental field "shall be based on the precautionary principle." In 2000 the European Commission clarified its approach of operationalising the precautionary principle in a risk assessment

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146 Annex to the Extended Impact Assessment on the proposal for extending the period of validity of Council Regulation (EC) No 975/1999 laying down the requirements for the implementation of development cooperation operations which contribute to the general objective of developing and consolidating democracy and the rule of law and to that of respecting human rights and fundamental freedoms, and of Council Regulation (EC) No 976/1999 laying down the requirements for the implementation of Community operations other than those of development cooperation, which, within the framework of Community cooperation policy, contribute to the general objective of developing and consolidating democracy and the rule of law and to that of respecting human rights and fundamental freedoms in third countries, 11. See http://ec.europa.eu/comm/europeaid/projects/eidhr/pdf/human-rights-regulations-impact-assessment_en.pdf (last accessed 15 July 2007).

147 United Nations Conference on Environment and Development, Rio Declaration on the Environment and Development (1992).

148 J. Dratwa, 'Social learning with the precautionary principle at the European Commission and the Codex Alimentarius', in *Decision Making within International Organizations*, B. Reinalda and B. Verbeek (eds) (London, Routledge, 2004), pp. 215-228.

149 O. Godard, 'Social decision-making under conditions of scientific controversy, expertise and the precautionary principle', in *Integrating scientific expertise into regulatory decision-making. National traditions and European innovations*, C. Joerges, K.-H. Ladeur, and E. Vos (eds) (Baden-Baden, Nomos, 1997), pp. 39-73.

framework in a communication,[150] as this choice is not a self-evident.[151] The precautionary principle's implications for regulatory decision-making occur at two different levels:

a) at the level of lawmaking: in a situation where potentially dangerous effects to public health or the environment deriving from a phenomenon, product or process have been identified but scientific evidence is not clear enough to determine the magnitude of the risk, decision-makers have a positive obligation to take action to avoid harm.
b) at the level of implementing measures: these should be designed in such a way that manufacturers of new products or technologies should carry the burden of proof; they should be required to show that their products or technologies will not cause undue harm to human health or the environment.

The degrees of implementation of the two tools may vary, since both impact assessment and the precautionary principle have dual roles as regulatory trade-off devices and legitimacy enhancing tools the question of their relationship is still an important one. Does IA reinforce the precautionary principle, as a superficial reading of the IA guidelines suggests,[152] or are the two rivals in a battle to become the main organizing instrument for dealing with value trade-offs in EU lawmaking? Although both options have proponents in the academic literature, the issue is not as hotly debated as might be expected.[153] One possible reason for this is the lack of clarity of the link with impact assessment as well as the perception that the topics belong to different 'research communities'.[154] But if a debate were conducted its two poles would consist of the 'environmentalists' on the one side (supporting a strong precautionary principle that prescribes action unless there is strong evidence that 'no action' will not lead to irreversible harm) and supporters of hard cost-benefit analysis (CBA) on the other (who favour the kind of impact assessment that makes sure

150 COM(2000) 1 final, p. 2.
151 J.S. Applegate, 'The Government Role in Scientific Research: Who Should Bridge the Data Gap in Chemical Regulation?' in *Rescuing Science from Politics. Regulation and the Distortion of Scientific Research*, W.E. Wagner and R. Steinzor (eds) (Cambridge, Cambridge University Press, 2006), pp. 260-261.
152 The IA Guidelines advise officials who are carrying out an IA to ask themselves "whether some of the impacts could be irreversible" and refers them to Annex 15 on the precautionary principle. SEC(2005) 791, p. 33.
153 J.B. Wiener, 'Better Regulation in Europe' (2006) 59 *Current Legal Problems*, 453 expresses similar surprise at the lack of debate on introducing impact assessment in the European Union, certainly after the 'aggressive' debates on the precautionary principle in the 1990s.
154 Even some recent publications on the precautionary principle in the EU do not mention Better Regulation or impact assessment, cf M.B.A. van Asselt and E. Vos, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 *Journal of Risk Research*, 313-336.

that regulation can only be put in place in the face of strong evidence proving a harm so great that it justifies the costs of regulation).[155]

One author who has attempted to stir up the debate on the issue of IA versus precautionary principle in the EU – and who clearly fall in the latter category – is Ragnar Löfstedt, declaring that '[t]o ensure better regulation, two regulatory philosophies have been put forward, namely the precautionary principle and impact assessment'.[156] He sees a clear dichotomy between the two and claims that many actors in the US view the European Better Regulation agenda as 'an opportunity to replace the irrational and non-scientific precautionary principle with scientific evidence-based decision-making'.[157] Löfstedt argues that the 'regulatory pendulum' has now swung away from the precautionary principle and slightly in the direction of impact assessment, although it could easily swing back in the future, for instance if 'another major regulatory scandal in the BSE vein occurs'.[158]

Things may well be a bit more nuanced. First of all there is economics literature arguing that the precautionary principle and cost-benefit analysis can be reconciled, when the irreversibility and the uncertainty inherent to the future benefits of a proposal are stressed as happens in some types of cost-benefit analysis.[159] Secondly, Löfstedt's own evidence for arguing that the use of precautionary principle is in decline, is a bit meagre. The fact that 'phrases such as the 'precautionary principle' are rarely used'[160] provides hardly sufficient ground to conclude that EU IA has not incorporated the precautionary principle. Careful dossier analysis is required, diving below the surface of 'precautionary speak', in order to establish the real impact of the precautionary principle in EU lawmaking. Now it is true that, authors belonging to the other side of the ideological spectrum on this issue, on the basis of environmental case studies have come to a similar conclusion, namely that 'that the precautionary principle has had little effect on actual policy-making'.[161] Yet it seems that the disagreement on what the precautionary principle should entail combined with some confusion as to what can be expected from it in the EU context can muddle these types of analysis. It is illustrative in this context that legislative proposals which to some observers

155 H. Doremus, 'Using Science in a Political World: The Importance of Transparency in Natural Resource Regulation', in *Rescuing Science from Politics*, W.E. Wagner and R. Steinzor (eds) (Cambridge, Cambridge University Press, 2006), p. 152.

156 R.E. Löfstedt, 'The Swing of the Regulatory Pendulum in Europe: From Precautionary Principle to (Regulatory) Impact Analysis' (2004) 28 *Journal of Risk and Uncertainty*, 237-260.

157 R.E. Löfstedt, 'The 'plateau-ing' of the European better regulation agenda: An analysis of activities carried out by the Barroso commission ' (2007) 10 *Journal of Risk Research*, 423-447.

158 *Ibid*., 443.

159 C. Gollier and N. Treich, 'Decision-Making Under Scientific Uncertainty: The Economics of the Precautionary Principle' (2003) 27 *Journal of Risk and Uncertainty*, 77-103.

160 Löfstedt (2004).

161 N. Eckley and H. Selin, 'All talk, little action: precaution and European chemicals regulation' (2004) 11 *Journal of European Public Policy*, 98.

are clearly based on the precautionary principle[162] does not provide enough incentives for a truly precautionary practice in the perception of others,[163] as is the case with REACH (see VI.1). Perhaps the more careful formulation by another author, Wiener, namely that 'the Better Regulation initiative, especially the use of IA, is moderating the earlier fervour for the Precautionary Principle'[164] is a more appropriate assessment of the situation.

Time to take a closer look at the IA framework and the framework put in place for operationalising the precautionary principle in EU lawmaking. The differences between the two 'regulatory philosophies' (as implemented in the EU) are in fact a lot smaller than Löfstedt's polarised analysis suggests. Both tools are used in the EU context as attempts to objectify 'common sense' rather than as strict 'decision generators'. The similarity with IA becomes clear where the Communication on the Precautionary Principle clarifies the requirement that precautionary measures must be 'based on an examination of the potential benefits and costs'.[165] Wiener views this as a redefinition of the precautionary principle by the Commission and observes a link with the introduction of IA, but it should be noted that the 2000 Communication predates the Action Plan on Better Regulation.[166]

> Examination of the pros and cons cannot be reduced to an economic cost-benefit analysis. It is wider in scope and includes non-economic considerations. However, examination of the pros and cons should include an economic cost-benefit analysis where this is appropriate and possible.[167]

This wording is by no means in contradiction with the IA framework.[168] On the contrary, the language is reminiscent of the only very light steer in the direction of cost-benefit analysis in the Impact Assessment Guidelines (see III.2). The Guidelines for their part merely invoke and summarise the Communication in an Annex, without adding concrete clues as to how to combine IA and policy-making on the basis of the precautionary principle.[169] The Communication is also keen to anticipate the fears of opponents of the precaution-

162 Transatlantic Consumer Dialogue, http://www.tacd.org/docs/?id=253 (last accessed 15 July 2007).
163 Hey, Jacob and Volkery (2006).
164 Wiener (2006), 460.
165 COM(2000) 1 final, p. 3.
166 Wiener (2006), 460.
167 COM(2000) 1 final, p. 18.
168 It is also in line with the Court of First Instance's decision in the *Pfizer* case which stipulated that some economic assessments is required, the Institutions still have a rather large degree of discretion in carrying out these assessments. *Pfizer Animal Health v Council*, Case No. T-13/99 [2002] ECR II-3305. See also N. De Sadeleer, 'The Precautionary Principle in EC Health and Environmental Law' (2006) 12 *European Law Journal,* 170-171.
169 SEC(2005) 791 (Annexes). Annex 15.

ary principles by stressing that 'the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions'.[170]

If the key is that the principle should only be invoked after every attempt has been made to gather evidence, could IA be the tool to trigger the precautionary principle? In that model, the precautionary principle would enter the scene if an IA has shown that the evidence available is inconclusive or insufficient. As the precautionary principle allows to override disagreement (or agreement that there is a lack of knowledge), the regulator can act and counter private rent-seeking That way the two would work together to achieve the optimally 'structured decision making process with detailed scientific and other objective information'.[171]

However, not all tension between the two can be neutralised completely by the flexibility of the respective frameworks. Whereas on the level of providing a structure for lawmaking, IA and the precautionary principle can be complementary, two problems remain:

1) It may be just more convenient to resort to precautionary measures rather than going through the effort of trying to collect more scientific data, especially when these measures are likely to be quite popular with European citizens. This concern is also present in the Report on 'Evaluation and Transparency' by one of the Governance Working Groups, which – as part of a plea that impact assessment should ask the right questions at the right time – states that 'the precautionary principle, as necessary and as modern as it may seem, should not preclude serious risk assessment balancing all costs and benefits of new legislation'.[172] Therefore the issue of the need to provide institutional incentives to carry out serious impact assessments is not solved.
2) At the level of implementing measures the precautionary principle – on one interpretation – can steer clearly in one substantive direction (namely giving the burden of proof to the industry), a direction that is not necessarily in line with Better Regulation and the IA framework. Of course this observation critically depends on a certain – more political – conception of Better Regulation, but one that is hard to deny. This is the tension that played out in the REACH case (see chapter VI).

III.6 Concluding remarks

The development of the European Commission's impact assessment procedure is characterised by the attempt to find a balance between retaining political discretion and enhancing objectivity in policy-making. Below the surface of

170 COM(2000) 1 final, p. 18.
171 *Ibid.*, p. 7.
172 EC Report on 'Evaluation and Transparency' (2001), p. 10.

the multiple objective the Commission attributes to IA, there seems to be an understandable preference for 'highlighting trade-offs' as the core of the IA regime. However, implementation of this model will not make the tensions inherent in policy-making disappear. IA is an iterative process, but it has got to stop somewhere. IA should genuinely explore various policy options including no action, but at the same time it is there to serve concrete policy-making.

One of the issues that illustrates these tensions best is the unresolved matter of whether an IA report should include a preferred policy option (see III.2.5). Will an open-ended IA report (one that just lists the options, possibly ranks them, but does not identify a preferred policy option) be used by the other institutions as a means of putting pressure on the Commission to agree to another option than the one finally chosen by the College of Commissioners? In certain extreme cases, this could amount to an undermining of the exclusive right of initiative. Another way of looking at the matter is to say that identifying a preferred policy option already in the stage of the IA is simply a matter of responsibility and a matter of using the IA for what it is meant to do: facilitate good policy making. Also if the IA contains no preferred option, what is then the appropriate document in which the Commission explains why it chooses one of the options in the IA over the others? Whereas it is envisageable that the IA is accompanied by a note to the College in which the services explain which option they recommend, it would be strange to publish the IA alongside the proposal with no explanation of how one relates to the other.

IV From Commission IA to EU IA

> Setting up these practices is a difficult but necessary business, but must not make the legislative cycle excessively protracted; nor must it constitute an obstacle to the European Union's freedom of action. The Commission's view is that a regulatory instrument which is better prepared and which is based on sound consultations and impact analyses will lead to the measure being adopted more readily and rapidly by the European Parliament and the Council.[1]

It was the Commission who first took concrete steps towards incorporating the use of IA into the legislative process and the fact that the previous chapter was devoted to the Commission approach to impact assessment reflects that. But the Commission evidently resents the fact that demands for Better Regulation are usually targeted towards itself rather than towards the other institutions or the Member States.[2] However, 'an intensive exchange of views has been going on between the Union institutions on this subject for years'[3] and – as the 2003 Report on Better Lawmaking puts it – '(t)he other institutions and Member States are progressively becoming involved in Better Regulation issues and developing their own positions and policies, which will increasingly have to be juxtaposed with those of the Commission.'[4] This chapter tells the story of how Commission IA became inter-institutionalised to such a degree that it is now warranted to speak of 'EU IA'. The first section describes the concept of IA as an inter-institutional tool and the process towards its institutionalisation. How IA was received and implemented in the European Parliament and the Council respectively will be set out in the second and third sections of this chapter.

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1 COM(2001) 726, p. 7.

2 This is inspired by a similar observation by De Burca on subsidiarity. De Búrca (1999), p. 36.

3 EP Kaufmann report (2001), 13. Cites the European Parliament resolution of 4 September 2001 on the Commission's 17th annual report on monitoring the application of Community law (1999) (COM(2000) 92), but that report deals mostly with implementation and SLIM is the only real regulatory reform issue it touches upon. See also the European Parliament resolution of 3 July 2001 on a draft Inter-Institutional Agreement on a more structured use of the recasting technique for legal acts.

4 COM(2003) 770 final.

IV.1 A JOINT RESPONSIBILITY

The process of 'inter-institutionalising' IA has seen some hurdles and has met resistance which illustrates that IA is much more than a bureaucratic tool. To pay due respect to the prerogatives of each of the institutions has always been a central concern as has been the realisation that Better Regulation must be a joint responsibility for it to have any real effect on the final legislative output. A further issue is the acknowledgement that some degree of homogeneity is necessary if IAs are to be used during the whole legislative cycle. On inter-institutional cooperation the Parliament pointed out that 'a European Impact Assessment (EIA)' as it was called on that occasion, 'only makes sense if the Commission, Council and Parliament operate in accordance with the same system and with the same standards' and expressed the wish to come to an agreement on the procedure to be followed. More specifically, joint 'criteria for quantifying the expenditure that legislative proposals generate, both in the EU as a whole and within the Member States'[5] should be developed according to the Doorn report.

Codecision as an institutional risk

From the perspective of the Commission the codecision procedure (Article 251 TEC) is sometimes perceived as a 'risk', because the Commission cannot control the final outcome. After the Commission puts forward a proposal, the final content of the legislative act will be determined in the legislative deliberations and negotiations between the Institutions with the Commission even completely out of the picture if the process reaches the conciliation stage. The discipline which IA imposes on the co-legislators can perhaps minimise that risk, by encouraging that each proposed amendment is supported by an analysis of potential impacts of this change. For a flowchart of the different steps in the codecision procedure please see figure II.1.

IV.1.1 Inter-Institutional Agreement on Better Lawmaking

The first delineation of the scope of application of IA in the European Parliament and the Council can be found the 2002 Action Plan, although it should be noted that in later policy documents the wording changed from 'substantial amendments' to 'substantive amendments'.

5 It is unclear whether this should be interpreted as a common methodology for measuring administrative burdens or for wider categories of costs as the Doorn report seems to equate administrative burdens with regulatory burdens.

> Action: Assessing the impact of substantial amendments by the European Parliament and Council. In keeping with the Commission's approach to its own proposals and as suggested by the report of the Mandelkern Group, measures should be adopted at interinstitutional level or an interinstitutional agreement drawn up to ensure that substantial modifications introduced by the European Parliament and Council to Commission proposals during the first reading undergo an evaluation or an impact assessment. Although an additional assessment of this kind might seem likely to slow down proceedings in certain cases, it should nevertheless ensure that the legislative act which is ultimately adopted is well founded, proportionate and does not entail excessive costs for the parties concerned.[6]

The Action Plan also mentions that the European Parliament and the Council will carry out the assessments whilst 'the Commission will conduct an initial impact assessment on the legislative proposal and will continue to deliver an opinion on the amendments of the European Parliament, in accordance with the Treaty'. The implementation was envisaged as 'gradually from 2003 onwards'.

With the adoption of the Inter-Institutional Agreement on Better Lawmaking 2003 in November 2003 Better Regulation and impact assessment became a 'joint responsibility' of the Institutions. Signed by the European Commission, the European Parliament and the Council in December 2003, it was the first document that contained an official commitment to extend the IA procedure to the European Parliament and the Council:

> Where the codecision procedure applies, the European Parliament and Council may, on the basis of jointly defined criteria and procedures, have impact assessments carried out prior to the adoption of any substantive amendment, either at first reading or at the conciliation stage. As soon as possible after this Agreement is adopted, the three Institutions will carry out an assessment of their respective experiences and will consider the possibility of establishing a common methodology.[7]

Apart from stipulating the common basis for impact assessment, the Inter-Institutional Agreement on Better Lawmaking lays down a common framework for several novelties in the European legislative process: the use of co-regulation and self regulation at the EU level, the use of impact assessment (also for substantive Council and Parliament amendments) and implementation of the Commission's new simplification programme.

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6 COM(2002) 278 final, pp. 15-16.

7 Inter-Institutional Agreement on Better Lawmaking (2003).

The status of an Inter-Institutional Agreement

Inter-Institutional Agreements (IIA) are an under-researched topic in legal and political science scholarship. This research lacuna has now partly been filled by a recent book by Von Alemann[8] and an issue of the European Law Journal dedicated to the subject. In this issue questions such as whether IIAs are 'an important means of informal constitution building in the EU' or even 'the fabric of European governance'[9] were addressed. Unfortunately the Inter-Institutional Agreement on Better Lawmaking is mentioned nowhere specifically in the special issue.

Eiselt and Slominski distinguish three different roles that IIAs can play depending on their relationship to primary law: (a) explicitly authorized specification of Treaty provisions via (b) not explicitly authorized specification of notoriously vague Treaty law to (c) pure political undertaking.[10]

IIAs can vary greatly in denomination, form, and content,[11] ruling out any generalised statements on their legal status and role. Hummer has summed up the different views on the legal status of IIAs:

> (a) on the one hand, IIAs are attributed to the extra-legal domain, meaning that institutions are merely politically bound to these agreements; (b) on the other hand, the possibility of legal effect is accepted, though it is not clearly explained; (c) lastly, IIAs are perceived to be somewhere in between non-binding and binding and assimilated to legal concepts known in other legal fields (international law, constitutional law, and so on).[12]

Eiselt and Slominski clearly accept the possibility of legal effect:

> It remains undisputed that IIAs cannot modify primary or secondary law. But within these legal boundaries, IIAs may eventually have legal effects deriving either from their Treaty basis or the intention of the drafting parties.[13]

For want of comprehensive jurisprudence of the European Court of Justice (ECJ) on IIAs, they look for indicators of legal bindingness in the more general case law on the subject and assume that contracting parties expressly intend to bind themselves – at least among themselves – if the wording is 'clear' or

8 F. von Alemann, *Die Handlungsform der interinstitutionellen Vereinbarung. Eine Untersuchung des Interorganverhältnisses der europäischen Verfassung* (Berlin/Heidelberg/New York, Springer, 2006).

9 P. Slominski, 'The Fabric of Governance: Interinstitutional Agreements in the EU' (2007) 13 *European Law Journal*, 2.

10 Eiselt and Slominski (2006), 215

11 W. Hummer, 'From 'Interinstitutional Agreements' to 'Interinstitutional Agencies/Offices'?' (2007) 13 *European Law Journal*, 47-74.

12 *Ibid*.

13 Eiselt and Slominski (2006), 202.

'sufficiently precise and unconditional'. Another clue of legally binding intention they mention is a provision that an IIA can only be amended by common agreement of the institutions involved.[14] Senden's thinking is along similar lines; she suggests that although IIAs are political rather than legal in nature, the use of wording like 'shall' may indicate intended legal effect, which would not be applicable in the case of the Inter-Institutional Agreement on Better Lawmaking.[15]

When negotiating IIAs the Institutions do not have to refer to a specific Treaty provision in order to pursue a given political goal as long as they do not amend Treaty law through IIAs. This means that it is likely that IIAs will be used to tackle issues that have not been touched upon or solved by European law, 'turning supposedly 'lower level' negotiations into 'higher level' ones characterised by conflicting interests and ideas'.[16] But this should not be taken to mean that negotiation outcomes will be clear and point unequivocally in one specific constitutional direction. On the contrary, the content of IIAs tends to be rather vague, 'leaving a great margin of interpretation and discretion, and– in combination with the lack of pertinent Treaty law–are thus closer to mere political declarations that cannot be regarded as legally binding'.[17] Eiselt and Slominski have found that IIAs on subjects that already have a solid basis in primary law are more likely to be – or develop into – legally relevant documents. IIAs on 'more elusive concepts such as subsidiarity, transparency, and democracy' tend to be legally ambiguous and often lacking legal relevance. However, Eiselt and Slominiski point out that these 'vaguer' IIAs can have considerable long-term political consequences, and could for instance pave the way for future Treaty amendments."[18] The Inter-Institutional Agreement on Better Lawmaking clearly falls into this latter category, where the relative absence of clear legal constraints means an opportunity to pre-empt fundamental constitutional choices.

In his contribution Hummer is concerned with the effect IIAs may have on the institutional balance, certainly cumulatively speaking. He argues that although under European constitutional law formal delegation of decision-making competencies are prohibited, this can occur informally through the mere conferral of consultative or participatory rights in IIAs. On the basis of a review of all 123 IIAs he documented between 1958-2005 he concluded that 'the sum of all IIAs has in fact had a significant impact on the 'institutional balance' – mainly, though not exclusively, because of the substantive and

14 *Ibid*., 210.
15 L. Senden, *Soft Law in European Community Law* (Oxford, Hart Publishing, 2004), p. 236.
16 Hummer (2006), 215.
17 *Ibid*.
18 D. Kietz and A. Maurer, 'The European Parliament in Treaty Reform: Predefining IGCs through Interinstitutional Agreements' (2007) 13 *European Law Journal*, 20-46; See also S. Puntscher Riekmann, 'The Cocoon of Power: Democratic Implications of Interinstitutional Agreements' (2007) 13 *European Law Journal*, pp. 4-19.

continuous strengthening of the European Parliament's position.'[19] Indeed, the view that the use of IIAs benefits the European Parliament in its quest for competence expansion at the expense of the Council and the Commission[20] seems to be the predominant one, although it is contested by Eiselt and Slominski in an earlier article.[21]

A more case-oriented approach is taken by Kietz and Maurer in their contribution to the same issue in which they investigate IIAs as 'path-makers for institutional change'. Their conclusion was that there is evidence that the IIAs they examined contributed to informal and incremental institutional 'development' or 'sub-constitutional change'. However their stronger hypothesis, namely that a gradual formalisation would take place of informal practices laid down in IIAs, only rang true for the case of comitology.[22]

IV.1.2 'Common Approach' of the Institutions

> This 'Common Approach' can be seen as the first step in developing a common methodology for impact assessment.[23]

High-Level Technical Group for Inter-institutional Cooperation (HLTG), consisting of high-ranked civil servants from the three Institutions, has been given the task to monitor the implementation of the Inter-institutional Agreement. The 'common methodology' mentioned in the IIA 2003[24] was negotiated in the course of 2005 by the 'correspondents group', a sub-group of the High-Level Technical Group for Inter-Institutional Cooperation. As the process of negotiation advanced it became increasingly clear that the agreement would contain a 'common framework' rather than a full 'common methodology'. After tense negotiations, agreement at the administrative level was finally reached in November 2005. Whereas the Council was quick to endorse, the European Parliament held out for longer as evidenced by this remark by MEP Lehne in the 4 April 2006 debate:

> An inter-institutional agreement has been in place since December 2003, according to which the Commission is, in principle, responsible for the impact assessment. That also means, though, that it is exercising a responsibility with and on behalf of the legislature, that is to say, for Parliament and the Council, and so we believe that we in this House, too, should have – and do have – a right to be consulted

19 Hummer (2006).
20 *Ibid*.
21 Eiselt and Slominski (2006).
22 Kietz and Maurer (2007), 46
23 European Commission website on Better Regulation, http://ec.europa.eu/governance/better_regulation/ii_coord_en.htm (last accessed 15 July 2007).
24 Inter-Institutional Agreement on Better Lawmaking (2003).

> as to how this impact assessment is carried out. I might add that that is also the reason why we, in the Conference of Presidents, initially delayed adopting a resolution on the follow-up administrative agreements, since these, of course, have to be renegotiated, not least in the light of the resolutions that we will be adopting on these four reports in May of this year.[25]

No 'common methodology' but a 'common approach'

The main principle enshrined in the Common Approach is that each Institution bears responsibility for assessing its own proposals or modifications as well as for choosing the means to be used for their impact assessment. This principle should be regarded in the light of the reservation made at the beginning of the Common Approach, namely that it is made without prejudice to the decision-making role and autonomy of each Institution and in line with their respective roles and responsibilities.

The rules and principles of EU IA set out in the Common Approach aim to balance this consideration with the resolution that '[t]he rigour, objectivity and comprehensive nature of the analysis should mean that the impact assessment is not a simple justification of the initiative or the substantive amendment'.[26] The Common Approach mentions the integrated and balanced coverage of potential impacts, meaning that social, economic and environmental ought to be covered. Also, where possible both short and long term costs and benefits should be assessed. Other elements emphasized by the Common Approach are integration of subsidiarity and proportionality tests into IA as well as the obligatory consideration of monitoring and evaluation. The requirement to consider a range of legislative and non-legislative options applies to the Commission only. On the whole, EU should be based on 'rigorous and comprehensive assessment based on accurate, objective and complete information' and take into account the principle of proportionate analysis (meaning concretely that '[t]he impact assessment's depth and scope will be determined by the likely impacts of the proposed action', see III.2.1). Furthermore the Common Approach prescribes transparency (all IAs are to be published on websites) as well as consultation for IAs ('where reasonably possible and without causing undue delay in the legislative process'). A final principle enshrined in the Common Approach is cooperation, in the sense that the Institutions agree to inform each other of ongoing IA work.

One particularly thorny issue for the Common Approach was the issue of revising the Commission IA. Can the European Parliament or the Council ask the Commission to revisit its impact assessment? This would mean a considerable amount of control over the discretionary policy-making processes

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25 Http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20060404+ITEM-013+DOC+XML+V0//EN&language=EN (last accessed 15 July 2007).

26 Common Approach to Impact Assessment (2005), para. 5.

in the Commission, something the latter would like to avoid for obvious reasons. The UK government put it very aptly:

> It should be pointed out, however, that the objective will generally not be formally to "revise" the Commission impact assessment. These fall entirely within the competence of the Commission and will be the basis on which it formulates legislative or non-legislative action. Additional work done by either the Council or Parliament will complement the Commission impact assessment. In many cases, the information in the Commission document will be the starting point for the other Institutions and will be supplemented by further information. The conclusions of the exercise will be used by the Council or Parliament to shape its own approach – e.g. by supporting or rejecting the amendment concerned. The Commission may revise its policy position by accepting an amendment, but is under no obligation to revise its impact assessment.[27]

In the end the compromise formulation in the Common Approach is carefully phrased:

> In duly justified cases, the Commission, on its own initiative or at the invitation of the European Parliament and/or the Council, may decide to complement its original impact assessment.[28]

IV.2 IA IN THE EUROPEAN PARLIAMENT

IV.2.1 Main issues of IA in the European Parliament

Parliamentary sovereignty?

A first important point to be made is that the explicit use of impact assessment by the European Parliament is unparalleled in the world. As the OECD has noted in its regulatory reform reports it is very rare for parliaments around the world to take measures for improving the quality of their regulatory outputs, leaving it to the administrative level to take action on regulatory quality.[29] Of course the European Parliament is no ordinary parliament: it is also the only parliament to lack the classical parliamentary power to initiate legislative proposals. And yet it is a very classical parliament in the sense that it is continuously protecting and if at all possible expanding its prerogatives.[30] These prerogatives are of a legislative nature only within the codecision

27 UK Government's Response to the House of Lords 31st report (2005), appendix 1, para. 71.
28 Common Approach to Impact Assessment (2005), para 12.
29 OECD (1997), p. 297.
30 R. Corbett, F. Jacobs and M. Shackleton, *The European Parliament* (London, John Harper Publishing, 2005).

procedure. The European Parliament has been seen to make effective and strategic use of the limited legislative powers it has been granted.[31] At times it has taken this task so seriously that Voermans and Konijnenbelt have wondered whether the European Parliament is developing into the 'legislative conscience of the European Union', even if its appetite for amendments undermines this predicate somewhat.[32]

The European Parliament has also been taking an active part in debates on various constitutional issues over the years, all with a view of enhancing its position. Apart from the high profile battle over the appointment of the new Commission in 2004,[33] negotiations have taken place on extending the role of the Parliament in comitology.[34] As a further example of constitutional activism on the part of the Parliament, the issue of whether a legislative instrument should be a first pillar instrument has led to high profile cases in front of the ECJ.[35] The general line taken by Parliament in these discussions has been that the lawmaking process can only fundamentally be improved by giving Parliament more powers and that any reduction of the Parliament's prerogatives will automatically lead to a delegitimization of the process (see II.2.2 on the parliamentary model of lawmaking).[36] The same vision underlies the Parliament's contributions to the inter-institutional dialogue on the use of impact assessment.

And yet the discourse of Better Regulation and impact assessment does not fit easily with the Parliament's argumentation in the debate which relies on democratic authority solely. Indeed the focus on the reasons and the evidence behind legislative proposals does not come natural to an institution habitually striving for consensus and valuing its political discretion so highly. As Wintgens has put it, the 'sovereignty of the ruler prevents his rules from being questioned in other than binary terms',[37] leaving questions of effectiveness and efficiency in the margins at best. When legislation is passed 'with

31 S. Douglas-Scott, 'The Law and Custom of a New Parliament', in *Constitutionalism and the Role of Parliaments*, K.S. Ziegler, D. Baranger, and A.W. Bradley (eds) (Oxford, Hart Publishing, 2007), pp. 79-95.

32 W.J.M. Voermans and W. Konijnenbelt, 'The European Parliament as the legislative conscience of the European Union' (2007) 32 *Legislação*, 57-76.

33 T. Beukers, 'The Barroso Drama. Enhancing Parliamentary Control Over the European Commission and the Member States. Constitutional Development Through Practice' (2006) 2 *European Constitutional Law Review*, 21-53.

34 Council decision of 17 July 2006 amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission (2006/512/EC), OJ L 200/11.

35 *Commission v. Council*, Case No. C-176/03 [2005] ECR I-7879.

36 A vision often shared in academic literature, see for instance Corbett, Jacobs and Shackleton (2005).

37 L.J. Wintgens, 'Rationality in Legislation – Legal Theory as Legisprudence: An Introduction', in *Legisprudence: A New Theoretical Approach to Legislation*, L.J. Wintgens (ed.), Proceedings of the Fourth Benelux-Scandinavian Symposium on Legal Theory (Oxford, Hart Publishing, 2002), p. 2.

knock-on requirements for further action', it is still possible to investigate alternative forms of regulation in order to try to find the most cost-effective option, but the 'political signal (...) that legislation will go ahead regardless of cost (...) weakens both the process and the incentives for bureaucrats to examine alternatives.'[38] This is just one example of why it is important in the eyes of many stakeholders to integrate IA into the legislative routine of Parliament: the most important thing about the European Parliament practising IA is not the exact design of impact assessment, but the discipline associated with it.

The potential culture change is greater for Parliament than it is for the Commission, which was already carrying out different kinds of ex ante evaluations before the introduction of IA (see III.5.2). Just compare the one line that is now spent on justifying a proposed amendment in reports from the Parliament to having to conduct a whole impact study. A requirement to conduct IAs on amendments could counter practices such as the tabling of amendments with the sole intention of dropping them as part of the negotiations. Some have even gone as far as to say that if the Parliament fails to abide by the principles of Better Regulation, this will undermine the Commission's efforts on IA.

There are also hopes that IA will help Parliament stand firm when faced with strong lobbies. It is common practice for lobby groups from different backgrounds to try to exert direct influence on the content of a new piece of legislation, by proposing 'ready-made' amendments to individual MEPs. A growing awareness of IA within the Parliament means that increasingly MEPs will insist that those lobby groups also show the impact of the proposed amendments.[39] Yet, the Parliament is still ill at ease with the participative and deliberative aspects of Better Regulation. Already in the 1998 report on Better Lawmaking De Búrca spots a 'tendency to which the Parliament has objected', namely that:

> the Commission appears to blend together a number of issues – those of clarity, simplicity, legislative transparency, and the overall quality of legislation, with its practices of advance consultation, 'impact assessment' of proposals and more fundamentally its 'judicious exercise' of the right of legislative initiative – into a broader conception of subsidiarity as a lighter, more participative, and more careful approach to Community policy-making.[40]

38 House of Lords 9th report (2005), p. 26.
39 Some already do this. Interview assistant MEP Jackson, 8 February 2007.
40 De Búrca (1999), p. 37.

Working method

The legislative working method so typical for the European Parliament, with the majority of the work carried out in Committees (which vote, unlike committees in many national parliaments), has been criticized for being detrimental to legitimacy:

> The characteristic focus of MEPs on scrutinising particular proposals for EU legislation, largely through committees, (...) plays an increasingly active role in shaping that legislation, but does little to engage the wider public.[41]

Use and production of IA in the Parliament will have to fit in with existing ways of distributing information to Committee members. In this system the rapporteur is a pivotal figure whose role – on one possible interpretation – can be seen as an 'informational device' providing 'valuable information about a piece of legislation at a small cost'[42] to his committee as well as to the plenary. Therefore the way the rapporteur engages with IA is crucial and will be explored further in the case studies (see chapters VI and VII).

IV.2.2 Parliamentary discourse on IA

The position of the European Parliament in the debate on the use of IA in the codecision procedure has already been addressed above on more than one occasion. However it is important to pay attention to specific contributions in order to understand the problems with implementation of IA in the Parliament. They are mostly scattered contributions reflecting political priorities, although there are also general parliamentary resolutions on the subject.

The early years

As early as 1996 the European Parliament already called for a set of criteria on the basis of which future legislative proposals would have to be assessed. This was in the context of its reaction to the Molitor report and the criteria proposed were the following:

(a) Is intervention absolutely necessary, or can self-regulation or other problem management or resolution mechanism be left to solve the problem or situation?
(b) If there is a need for action, what are the available options?
(c) The costs and benefits of the planned measure for the state and the persons concerned should then be assessed (cost-benefit analysis). Do the results of

41 Wallace (2005), p. 495.
42 G. McElroy, 'Legislative Politics', in *Handbook of European Union Politics*, K.E. Jorgensen, M.A. Pollack, and B. Rosamond (eds) (London, Sage, 2006), p. 181.

the analysis justify the planned measure even when the costs exceed the benefits?

(d) Finally, there must be an assessment, based on the preceding steps in the test process, of whether the proposal should progress to become draft legislation, or whether that would not be justified.[43]

Several years later, as Better Regulation appears on the EU agenda in a more serious way, the European Parliament starts stressing the link between IA and the preservation of parliamentary powers in the Kaufmann report, the highly critical reaction to the Commission's White Paper on Governance:

> [The Parliament] warns the Commission (...) against taking measures in the legislative sphere which might affect the roles of Parliament and the Council in the legislative process before Parliament has been fully consulted.[44]

And throughout the development of Better Regulation as an inter-institutional issue there have been signs that – as Hutton put it at a hearing in front of the House of Lords – 'within the European Parliament there are concerns about what [the IA] agenda means'.[45]

In fact the non-negotiable vision that parliamentary power equals legitimacy and that any institutional innovation should be made to fit that mould is what seems to have kept together the two 'schools' that exist within the Parliament: the 'IA believers' and the 'IA sceptics'. The believers are those who are enthusiastic about IA and would like to see an increased used of the tool, at least as long as objectivity of the analysis can be ensured. The sceptics take a suspicious stance on IA, viewing it mainly as a constraint on the pursuit of political preferences by MEPs, or in other words an illegitimate disciplining of the European Parliament.

The European Parliament declared itself by a large majority in favour of the use of impact assessment in a resolution on 20 April 2004 on assessment of the impact of Community legislation and the consultation procedures[46] also known as the 'Doorn report', after its author. The report voices the idea that 'effective democratic accountability is only possible if Parliament has sufficient information on the consequences of legislation on social, economic and environmental aspects'. It defines IA as 'a straightforward mapping out of the consequences on social, economic and environmental aspects, as well as a mapping out of the policy alternatives that are available to the legislator

43 EP report on the report of the group of independent experts on simplification of Community legislation and administrative provisions, Committee on Legal Affairs and Citizens' Rights, Rapporteur: Mrs Marlies Mosiek-Urbahn, 12 June 1996 (PE 216.339/fin. A4-0201/96).

44 EP Kaufmann report (2001), p. 8.

45 Mr Hutton on the Better Regulation agenda, see EP Doorn report (2004), p. 6.

46 OJ C 104 E, p. 146.

in that scenario'.[47] After confirming that 'impact assessment is in no way a substitute for the democratic decision-making process', the report makes the interesting assertion – unfortunately without providing any reference – that 'experience in countries where impact assessment is carried out demonstrates that it results in improved legislation and simplifies parliamentary scrutiny'.[48] In its contribution to the 5th biannual report of COSAC the European Parliament wrote:

> The 'better regulation' debate is seen by the EP as an occasion for reflection on legislation as a process designed to achieve clearly defined policy goals by committing and involving all stakeholders during all phases of the process from preparation to enforcement.[49]

This language marks a shift in the thinking about IA within the Parliament: from a threat to democracy to an extra means of control over the pre-legislative stage. Salient is also the choice of words in the following sentence

> [The European Parliament p]roposes *to allow* impact assessment to be carried out on initiatives that the Commission presents in its annual policy strategy or its work programme and on amendments by the European Parliament and the European Council that will have a substantial impact on social, economic and environmental aspects.[50]

Does the Parliament mean to say it has or should have a say in the internal 'household' rules of the Commission or does it hereby imply that the impact assessment procedure goes much further than that? It is more likely that this curious choice of words should simply be attributed to the disorientation that characterises the beginning phase of EU Better Regulation.

The first Doorn report also argues for a 'cost threshold' to be agreed between Commission, Parliament and Council. In order to determine whether the estimated costs transgress the threshold and warrants a full impact assessment, a preliminary 'cost assessment' would have to be made. A cost threshold would also apply to IA on substantive amendments. This proposal has never been adopted and it is still only the principle of proportionate analysis (see III.2.1) that determines the extent of assessment. The report proposes an audit to monitor the IA process the results of which would then be reported with the legislative proposal, but the exact implications remain unclear.

47 EP Doorn report (2004), p. 6.
48 *Ibid*.
49 COSAC, Annex to the 5th biannual report (2006), p. 75.
50 EP Doorn report (2004). Emphasis AM.

The debate continues

After the adoption of the Doorn report I by the European Parliament plenary, the debate continued with a handful MEPs acting as prominent instigators. MEP McCarthy wrote the following in a newspaper article in the European Voice:

> The Parliament, too, must play a full role and its democratic prerogative as a co-legislator must be respected, so that it can apply the necessary checks and balances in the legislative process. We are committing resources to carrying out impact assessments on key proposals, which will enable us to make more informed decisions, when faced with competing stakeholders' interests, arguing for different approaches. Thousands of amendments tabled on controversial legislative proposals are counter-productive to achieving clear and precise laws.[51]

MEP Caroline Jackson – chairwoman of the Environment Committee at the time – also drew attention to the growing importance of IA in a speech.[52] She explained how legislative proposals used to be based on rather limited cost assessments:

> [i]f MEPs or anyone else raised difficulties about the cost, they were told that the cost of non-action greatly outweighed the cost of action.

But she asserted that the mood has changed now and governments, local authorities, as well as citizens of the EU 'are a lot more curious and questioning about the cost of what is proposed'. She expressed the expectation that the impact assessments produced by the Commission – citing those attached to the draft proposals on groundwater and on batteries as examples – would help the legislative debates in the Parliament. Jackson wondered '[w]hat happens if the impact assessments conflict?' but hoped that the answer would be given in the common methodology, which – as we have seen – is not the case.

Taking a look at the Parliament's report on the draft constitutional treaty, it is worth noting that the Legal Affairs Committee proposed to add wording on Better Regulation. The suggestion of the Committee was to add the phrase 'although the powers of the European Parliament concerning Better Regulation and control of the exercise of implementing powers by the Commission are not laid down expressly in the Constitution' in the beginning of the sentence.[53] Although this wording did not make it to the final text, it reflects a growing

51 McCarthy and Frassoni (2005).

52 MEP Caroline Jackson, Speech to the National Society for Clean Air, 'Europe – still setting the environmental agenda?', 10 December 2003. Http://www.carolinejackson-mep.org.uk/page.php?pid=17 (last accessed 26 October 2006).

53 EP Report on the Treaty establishing a Constitution for Europe (2004), 101. The proposal was to add this wording to paragraph 4, point (g) of the main text.

sense that shifting powers are associated with Better Regulation and that this could have been an issue for a constitutional text to deal with.

There have also been parliamentary contributions to the debate on what the substantive framework of EU IA should look like. A meeting of the Social Affairs and Employment Committee in January 2006 discussed impact assessment policy. MEP Hughes (PSE/UK) (replacing MEP Christensen) stated that business impact assessments should take account of social impact assessments as well. MEPs Crepaldi and Da Roit presented a study on 'social impact assessment',[54] arguing that social impacts tend to be neglected, which – if true – would go against the common conviction that environmental impacts are the neglected category.[55]

Shared criteria for IA?

On 18 June 2004, Pat Cox said in a speech addressed to the European Council:

> Thirdly, we need to agree as soon as possible on common criteria and a common methodology for impact assessment in the legislative procedure, to better measure the budgetary and economic effects of what we do on employment, competitiveness and the environment. Again, if we do not commit will and resources to the task, the quality of legislative output will suffer and ultimately, too, it will disadvantage the European citizen.

In a reaction to the statement by the President of the Commission on the Commission's strategic political orientations on 14 December 2004, MEP Monica Frassoni (Verts/ALE) stated on behalf of her Group:

> The second concerns the issue of impact assessment. New laws should not be assessed arbitrarily but in a way that is based on uniformly applied criteria. The European Parliament is moving slowly on this front. We know that companies and the economic world in general are much more active in this field. We must encourage the Commission and Parliament to assess new laws on the criteria of sustainability and social impact as well.

During the debate on 'Screening of the legislative proposals pending before the legislator' on Tuesday 27 September 2005 in Strasbourg MEP Frassoni interrogated Vice-President Verheugen:

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54 According to the authors of this report, less than one-fifth of the documents "analysed possible social aspects. Especially documents in economic field tend to concentrate more on the aspects of employment. The reporters suggested that social aspects should be considered and more involved".

55 Istituto per la ricerca sociale, 'The inclusion of social elements in Impact Assessment' (2006).

> I also think that in connection with the impact assessment question and other topics that you have raised here, such as screening, there are outstanding problems that may seem innocent enough but unfortunately are not: just look at the demolition job that you – you yourself and the Commissioner and President Barroso – are performing on REACH and have already performed on the pollution strategy. I therefore sincerely expect a clear answer from you on these two topics.

Verheugen replied:

> The whole question of the impact assessment is a difficult one, and one that I did have something to say about. For its own part, the Commission has decided that it will no longer be making proposals before a comprehensive assessment of the costs resulting from them has been carried out. Although that is an internal procedure within the Commission, we will present you with the results from it at the same time as we forward proposals to you. Speaking personally, I take the very definite view that a further impact assessment will of course be needed if the legislator does what it is there to do and makes substantial changes to the Commission proposal. That, though, is a decision for you yourselves to take, for it is you, and not the Commission, that are the legislative body; if you say that you can adopt an act even without an impact assessment, then that is your decision and your responsibility. I would, however, advise that we should, together, look for a way in which we can come up with a generally acceptable method of assessing the impact of legislation.

On this occasion Verheugen referred to impact assessment as 'the new method whereby we draft legislation' and told the Parliament that the actual result of this project would entail 'a significant increase in its quality, and you, the Members of the European Parliament, being the people who make the laws, will be enabled to arrive at a very precise account of the costs and benefits of every individual decision'.

When President Barroso presented the Legislative and Work Programme for 2005 to the European Parliament at the presentation of on 26 January 2005, he explicitly added that

> [t]hese initiatives will be submitted for an impact assessment in order to ensure that the principles of proportionality, subsidiarity and added value to the Union are properly implemented.

MEP Lehne (PPE-DE) on the same occasion stated that the legal policy experts in the Group of the European People's Party (Christian Democrats) and European Democrats were

> glad to see that your programme includes better regulation and impact assessment, which could be summed up as the business of estimating the cost of compliance with laws.

He continued to state that his Committee attached

> particular importance to the text of this agreement being taken seriously and to you not merely signing affirmations, like the one your predecessor signed in December 2003. That means that proper consultation processes have to be gone through, and there also – quite crucially – has to be sufficient transparency and, in contrast to what has often, unfortunately, happened with Commission proposals, *a real impact assessment rather than one that can be said to do no more than help to justify the proposal*.[56]

The second Doorn report,[57] adopted as part of a series of four reports related to Better Regulation in May 2006 contained no deviation from the line taken in the first Doorn report. Apart from noting the need for every legislative proposal to be accompanied by an impact assessment, it welcomed the development of impact assessments in the preparatory phase but qualified this statement with the familiar warning:

> that they cannot replace political debates about the advantages and disadvantages of laws; emphasizes that the interests of consumers, companies and citizens cannot be reduced to a mere cost-benefit analysis.

The rapporteur clarified this further by adding that 'laws should be executed under the full responsibility of the institutions themselves, in accordance with their political priorities'. The report also asks 'for full transparency during the preparatory phase, for justifications based on the results sought, and for further precision where necessary'. It is a bit unclear what is meant by 'justifications based on the results sought', but it seems that the rapporteur does not mean that IAs should contain justifications of proposals as he wrote that 'the impact assessment often resembles a justification of the proposal rather than an actual objective assessment'.[58]

His overall assessment of the Commission's track record in IA is finding fault as well:

> [T]he impact assessment carried out by the Commission does not consistently follow the same methodology and is therefore of varying quality.[59]

It should be noted that the Commission is being judged here on the basis of other standards than its own. In the Commission's IA Guidelines it is promoted

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56 European Parliament, Debate on Strategic guidelines/Legislative and work programme for 2005, Wednesday, 26 January 2005, Brussels, http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20050126+ITEM-006+DOC+XML+V0//EN(last accessed 16 July 2007). Emphasis AM.

57 EP Doorn report (2006).

58 *Ibid.*, recital.

59 *Ibid.*, p. 4.

as good practice to base the choice of methodology for a certain IA on the specificities of the case at hand. Finally the Doorn report II insisted on 'the importance of common guidelines in full respect of the three Lisbon pillars' as well as on a proper budget.[60]

'In-house assessment body' or 'independent agency'?

Certain aspects of the American RIA system, in particular the strict review by the Office for Management and Budget receive praise from individuals in the Parliament.[61] MEP Caroline Jackson introduced the debate on who should conduct IAs and who should review them aptly in a speech:

> Not that such [IAs] will be unchallenged. At the moment they are carried out for the Commission by people selected by the Commission. This element of in-house selection is open to criticism as [it is] likely to produce the results that the Commission wants. There is already trouble over the viability of the impact assessment on the draft chemicals regulation [REACH, AM], where the industry contests the conclusions reached by the consultants the Commission selected, and wants a fully external assessment. MEPs are attracted by the idea of setting up a European equivalent to the Office of Management and Budgets in the Congress. The OMB, unlike the embryonic European system, is seen as a body separate from those producing the legislation on which it comments.[62]

The issue was already included in the first Doorn report. In the explanatory statement the rapporteur pleads in favour of an independent institution that can monitor 'the implementation of an impact assessment'. This could prevent impact assessment being 'turned into an instrument for opposing undesired legislation in an undemocratic manner'.[63] The report calls it 'unfortunate that the Commission proposal[64] does not mention any such independent institution' and proposes that both amendments and parliamentary impact assessments could be monitored by an independent body coming under the President of Parliament.

One of the MEPs strongly in favour of establishing an in-house assessment agency is Jacques Toubon. He stated:

> I believe that it is of fundamental importance, in order to go beyond mere contestation of the Commission's IA, to have our own evaluation system in the Parliament. I would be in favour of a system in which we have in the Parliament

60 *Ibid.*, p. 12.
61 Interview MEP Cederschiöld.
62 Dr Caroline Jackson MEP: Speech to the National Society for Clean Air 10 December 2003 "Europe – still setting the environmental agenda?". Http://www.carolinejackson-mep.org.uk/page.php?pid=17 (last accessed 26 October 2006).
63 EP Doorn report (2004).
64 Presumably COM(2002) 276 is meant here.

> an in-house evaluation agency at our disposal comprised of officials but it is also possible to work with specialised experts who are contracted.(…) I know that the Commission is vehemently opposed to this on the grounds that this would interfere with its right of initiative, but I think that it is the true way forward.[65]

The phrase 'in order to go beyond mere contestation of the Commission's IA' is interesting because the section below on IA in practice (IV.2.4) shows that currently the European Parliament often does not manage to go beyond that. On the academic front the idea of a review body also receives considerable support. One author has even tied the chances of success of parliamentary review of IA to the creation of an independent IA review body. Comparing the EU situation to the US, where there is no IA requirement for legislative proposals in Congress and the congressional power to reject an agency regulation on the basis of the Congressional Review Act 1996, Wiener writes:

> Adding an expert body in the US Congress and in the European Parliament equipped to perform IA (as a counterpart to IA by the White House and the Commission) could raise the Parliament's stature and enable it to engage actively in reasoned debate over regulatory policy (to reject, revise or prompt policies, as the net benefits warrant). […] But if no such expert body is created, then Congressional or Parliamentary review of regulatory policy could be seriously dysfunctional: driven by the vicissitudes of political winds and caprice, unrelated to societal net benefits, it could mark a return to horse trading among parties and parochialisms that would harm rather than help yield Better Regulation.[66]

The question to what extent Commission IAs should be carried out by a body that is at arm's length from the actual decision-making on legislation is also hotly debated. At the hearing at the Select Committee on European Union of the House of Lords, a few members of the European Parliament Legal Affairs Committee gave evidence on European Contract Law, Rome II, and Better Regulation.[67] Disagreement about the question who should conduct the impact assessment gave rise to a short debate between MEP Lehne and MEP McCarthy. Lehne argued that his conclusions from a study trip to Washington DC were that independence is crucial to the impact assessment procedure. He said:

> It is clear that the key responsibility for the impact assessment is with the Commission. From my point of view it is logical because they have the monopoly on creating proposals for legislation and if they have the monopoly it is logical that it starts there with the impact assessment.

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65 Interview Jacques Toubon. Original statement in French; translation AM.
66 House of Lords 8th report (2005).
67 House of Lords 9th report (2005), p. 7 of the Minutes of Evidence.

However he went on to state that '[t]he Commission should think about taking this out of the normal bureaucracy'. McCarthy said that she did not fully share that view:

> I do believe there should be checks and balances in terms of what comes out of the Commission proposal but I believe, also, that if you do not give the responsibility to those drafting legislation that they need to take into account the impact of their own drafting then it is very easy for them to pass the buck and I do not think you improve the legislative process because you continue to have the same process whereby there are no consequences.

In other words, her argument was that the institutional learning element is lost if you do not have one and the same person (or unit) prepare both the proposal and the impact assessment. But the MEPs agreed that, at least, an independent oversight body should be established to issue, in the words of McCarthy a 'certificate of assurance'.

Synthesis

From the scattered and politically flavoured discourse described above, one main issue emerges rather clearly: the European Parliament perceives the eventuality that IA is being used as an instrument for opposing legislation in general and European Parliament amendments in particular as the main institutional risk. This is however counterbalanced by the opportunity of having more of a real choice between different regulatory options, making up to some extent for its lack of right of initiative. This could be as limited as 'being better informed', choosing between alternatives within the Commission proposal (changes that can be brought about by amendment but which are clearer or more obvious because of IA). Or, in the longer term at least, it could go as far as encroaching upon the exclusive right of initiative of the Commission, if the Commission increasingly finds itself forced to accept the 'invitation from the Parliament to review certain parts of the original IA in the light of the political developments. Parliament cannot formally require the Commission to motivate legislative proposals better, so it hopes to be able to achieve this by making a little detour via IA. The Commission can be 'shamed and blamed' through IA, only this time it is an official part of the inter-institutional dialogue. Parliament furthermore wants full discretion when it comes to deciding when an amendment is substantive to such an extent that it needs an IA. It also would like to be able to outsource the IA when it sees fit, because it claims it has too little in-house capacity for thorough IA analysis.

IV.2.3 Procedures for IA in Parliament

Debating the political implications of the introduction of IA for the European Parliament is one thing, practically implementing the new procedure into the lawmaking routine is quite another. The organizational side of the matter is perhaps the biggest problems for implementing IA in the European Parliament. The question 'who, in what stage, with what (and how much) money can command the IA studies' is occupying people who work in the administration of the EP. Indeed, the main axes along which organizational problems revolve are

- Human resources and expertise;
- Time frame;
- Financial resources.

In early 2004 a working group was established within Parliament's Secretariat to 'see how the instrument of impact assessment could be improved within the new Parliament'.[68] Also on the technocratic level within the Parliament discussions started taking place on how to organize impact assessment within the Committee work. Newer and more specific discussions have taken off after the adoption of the 'Common Approach to Impact Assessment' in November 2005. Working methods in Committees have to be adopted for a proper 'handling of Commission proposals and impact statements'.[69]

At a conference on impact assessment organized by the European Commission on 20 March 2006 it was submitted that IAs will mostly be done by contracting out the assessment studies, just like the Environment Committee had already been doing for their 'rapid impact assessments'. Sources within the Parliament report that a new framework contract agreed by Directorate A has triggered more requests for IA work at the Committee level. But although the preference for having IA studies done externally is understandable, it comes with some problems: how to make sure that these IAs contain relevant information (sceptics will say: 'information that support the existing political preferences') and that they are of good quality? This is why it is important that officials working in the European Parliament are familiar with IA. In September 2005 training on IA has started with a more in-depth training seminar held on 8-9 February 2007. Internal practical guidelines for parliamentary committees are in preparation and will be available soon. The European Parliament

68 European Parliament, Committee on the Environment Public Health and Consumer Policy, Summary record of Coordinators meeting, Monday, 16 February 2004, p. 4 para. (ii) on Impact assessment. See Http://www.europarl.eu.int/comparl/envi/pdf/coordinators/coord20040216.pdf (last accessed 27 March 2006).

69 European Parliament, Committee on the Environment, Public Health and Food Safety, Summary record of the Coordinators meeting, 30 January 2006, 6. See http://www.europarl.eu.int/comparl/envi/pdf/coordinators/coord20060130.pdf (last accessed 27 March 2006).

policy departments are also undertaking an evaluation of the first cases of European Parliament IA.

In terms of problems caused by the time frame it is important to note that although in the first reading the European Parliament may not have legal deadlines, the political ones are far from trivial. In the second reading hard legal deadlines are even a reality; less than ideal circumstances for carrying out costly and complicated impact assessments. On the financial front things improved recently. The year 2006 was the first in which a special budget for IA was foreseen, namely 500,000 euros. In 2007 the budget was increased to 700,000 euros.

The latest procedural novelty is that the Parliament's Secretariat produces 'impact assessment fact sheets' containing basic information on the policy options and impacts mentioned in Commission IAs to facilitate the use of Commission IAs in the Parliament. These fact sheets are put online next to the other types of fact sheets, such as financial statements, file synopsis sheets and multiple-file summaries.[70]

IV.2.4 IA practice in the European Parliament

There are two official modes of use of IA in the European Parliament:

- scrutiny of Commission IAs, possibly leading to an invitation to the Commission to complement its IA;[71]
- production of IAs on its own substantive amendments.[72]

However, the different uses of IA by the European Parliament in practice do not follow this distinction very neatly. True, the production of IAs an amendment is a fairly specific subject, the practice of which can be rather clearly delineated but which is also surprisingly little known (both the existence of this option, as well as the means to achieve it). Talking of 'production of IAs' by the EP, the European Parliament is actually much more active in producing studies, that are sometimes called IA, sometimes not and which serve as a 'second opinion' on the Commission's findings. This can be seen as 'scrutiny

70 http://www.europarl.europa.eu/oeil/FindNewFicheByType.do?xpath=%2Foeil%2Fnews%2Ffiche&type=10260&nbrDays=30&startIndex=1&pageSize=10&countEStat=true&searchCriteria=Impact%20assessment (last accessed 15 July 2007).

71 In conformity with para. 12 of the Common Approach. At the Conference on Impact Assessment organized by the European Commission on 20 March 2006 in Brussels the speaker from the European Parliament named Pesticides Regulation and the Thematic strategy on Marine Environment as dossiers in which possibly a request will be made to the Commission to complement its IAs.

72 In conformity with article 30 of the 2003 Inter-Institutional Agreement on Better Lawmaking, which states that the European Parliament may, where the codecision procedure applies "have impact assessments carried out prior to the adoption of any substantive amendment, either at first reading or at the conciliation stage".

of the Commission IA' except for the fact that in some cases the Commission IA is not even ready when the European Parliament study is produced. Another use of IA in the European Parliament which does align with the pure concept of 'scrutiny of Commission IAs' is the use of the absence of an IA, or perceived flaws in the IA procedure as a self-standing argument in the debate. In the light of this the following functional categorisation of the use of IA in the European Parliament is proposed.

Table IV.1: Categories of EP IA

Categories of EP IA	*Subcategories*
Scrutiny of Commission IA	· substantive (questions, invisible scrutiny) · procedural (flaws in IA procedure)
EP IA on amendments	· IAs labelled as such · IAs not labelled as such
EP IA not on amendments	· pre-emptive strike · background studies
Making use of the absence of an IA	· Requests for IA · 'No IA' as trump

Scrutiny of Commission IAs

Substantive

One of the most high-profile and controversial proposals in recent years was the one for a Directive on Services in the Internal Market.[73] As it was positioned at the intersection of internal market and labour relations controversy was inevitable. And after a rather calm and technocratic preparation of the proposal, it caught the attention of some campaigners in the run-up to the French referendum. An impact assessment was produced for this initiative as part of the pilot project in the Commission, but played only a minor role it played in the legislative debate. The only reference[74] to the Commission impact assessment in the European Parliament report[75] is by the Committee on Women's rights and gender equality:

73 SEC(2004) 21.

74 Although the Committee on Employment and Social Affairs refers to an 'impact study' entitled 'Towards a European Directive on Services in the Internal Market: Analysing the Legal Repercussions of the Draft Services Directive and its Impact on National Services Regulations', Wouter Gekiere, Institute for European Law, Catholic University Leuven, 24 September 2004.

75 A6-0409/2005 of 15 December 2005.

> The impact assessment, made by the Commission, is rather ambiguous. While recognising that it is very difficult to provide a reliable estimate of the effect of barriers to services on the EU economy, it states that millions of jobs will be created. There is still no comprehensive analysis on the problematic of creation of jobs and better quality of jobs within the EU. The social dimension and an impact assessment of social and employment effects are missing. Research shows that previous liberalisations have led to the destruction of existing jobs and the erosion of social cohesion. A more detailed analysis is needed, that specifies the kind of services likely to suffer from barriers, or benefit in terms of employment growth from the removal of barriers.[76]

The opinion then proceeds with some kind of alternative impact assessment. In the same vein there was a strong lobby by MEP Anne van Lancker[77] and the Social Platform for a 'full social impact assessment'. The Social Platform wrote the following:

> The complexity of the proposal and its implications means that it is extremely difficult to get a clear idea of the potential impacts of the directive, including on social service providers and their users. The UK Government, for example, states that 'no suitable model to estimate the effects of the liberalisation proposed by the Directive currently exists,' in its consultation paper on the directive (www.dti.gov.uk). However, *it is unacceptable to forge ahead without a proper impact assessment*. The *Commission's 'Extended Impact Assessment'*, which was published with the proposal, *is inadequate*. There is therefore an *urgent need for more effort to undertake a full impact assessment of the directive – in particular as to its effect on social services of general interest*. The Social Platform thus supports the proposal of Anne van Lancker MEP for a thorough social assessment of the proposed directive (…) Such an impact assessment should involve all relevant stakeholders including social NGOs who provide significant numbers of services in the social and care sectors throughout the EU.[78]

MEP Kirkhope (PPE-DE) at the continuation of the debate on the Commission's Legislative and Work Programme for 2005 on 21 February 2005:

> The Commission must be as efficient as it is requiring our businesses and citizens to be. He rightly talks about better regulation, but the priority must be less regulation and, crucially, that legislation must be subject to full impact assessment. British Conservative MEPs have been at the forefront of campaigning for less regulation and enforcing such impact assessments. I look forward to, and am confident that I will see, some progress soon on all these issues in relation to the Services Directive, which I am so pleased he supports.

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76 Draftsman Raül Romeva I Rueda, p. 338.

77 Working Document to the Employment and Social Affairs Committee, 25 March 2004.

78 Position paper, 'Comments from the Social Platform for the European Parliament Hearing on Services in the Internal Market', 11th November 2004. Also repeated in the summary record of the Services Directive Hearing – 11 November 2004, 4. Emphasis AM.

The argument that the impact assessment was not properly done and that consequently the Commission should come up with a new IA, usually on a specific aspect of the proposal, is a recurring one. Often this is done seemingly without much awareness of the content of the Commission IA in question and of the Commission IA system. Obviously, calling for more IA work by the Commission is a convenient type of opposition is convenient because requiring few resources on the part of the European Parliament. Any awareness of the possibility for the European Parliament to produce its own IAs often seems to be lacking in these criticisms.

In the case of the Services Directive however, the content of the Commission IA did not go completely unnoticed. A representative of the European Trade Union Confederation, claimed that the Commission's impact assessment of the proposal 'revealed a large number of discrepancies' regarding the effects on employment law.[79] The Commission is accused of exaggerating the potential benefits of the Directive by on the one hand recognising that it is very difficult to provide a reliable global estimate of the effect of barriers to services on the EU economy and on the other hand stating that millions of jobs will be created.[80]

In the debate on the Services Directive some have gone one step further and lamented the absence of an impact assessment.[81] Often, when this type of statement is made (see also the case study on the data retention dossier in chapter VII) it is not clear whether the MEP in question is unaware of the existence of a Commission IA or is merely being rhetorical ('bad IA = no IA in the proper sense of the word'). In any case, this manner of speaking can also be found with official bodies: the opinion of the European Economic and Social Committee[82] implies that a comprehensive IA of the Services Directive is lacking.[83]

Another example of a Commission IA that has been scrutinised is the one on the collective management of copyright. MEP Toubon said – in the interview on the pre-packaging case study (see VII.1) – that the societies concerned had come to see him claiming the Commission IA contained manifest falsehoods.[84]

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79 European Parliament, Notice to members No 12/2004, 'Public hearing of 11 November 2004 on services in the internal market – summary, 11 November 2004.

80 Remarks by Mrs. Catelene Passchier, Confederal secretary, European Trade Union Confederation (ETUC), Consolidated Proceedings of the Public Hearing on the proposal for a Directive on Services in the Internal Market, 11 November 2004, European Parliament, p. 103.

81 Jean Lambert (Greens/ EFA), according to: European Parliament, press release, 'Parliament debates the Services Directive ahead of important vote', 15 February 2006.

82 Opinion of the European Economic and Social Committee of 10 February 2005 on the Proposal for a Directive of the European Parliament and of the Council on services in the internal market. COM(2004) 2 final – 2004/0001 (COD).

83 COM(2004) 2 final – 2004/0001 (COD).

84 Interview Jacques Toubon.

He replied by asking the Commission questions the truthfulness of the information in the IA.

In their explanations of vote during the debate on Wednesday 26 October 2005 in Strasbourg on the Recommendation for second reading on the Proposal for a regulation of the European Parliament and of the Council on certain fluorinated greenhouse gases[85] two members explicitly referred to impact assessments. The first MEP, Françoise Grossetête (PPE-DE) talked about substance, explaining that she was opposed to expanding the list of prohibited products and equipment, *in particular because of the impact assessments carried out by the Commission* and because of the absence of alternative solutions in the medium term.[86]

A final example is the spare car parts proposal: in a list of questions for the hearing on 21 April 2005 two questions were IA related:

> 3. In your opinion, do the results of the EPEC-Study and the Commission's impact assessment justify the liberalisation of the spare part market ?
> 4. Are the collected data for the Commission's extended impact assessment based on the EPEC study in your opinion sufficient to assess the economic and social impact of a liberalisation of the spare parts market on industry, trade, consumers, employment and environment or should additional data be collected to complete the impact assessment?[87]

Procedural

One example of what 'procedural scrutiny' might look like is the matter of the liberalisation of games and lotteries. The Commission had put out a tender for a study on the legal and economic aspects of gambling and games of chance as part as the preparation for a possible proposal for a directive on the liberalisation of the internal market for games. The Swiss Institute of Comparative Law won the tender and subcontracted the Centre for the Study of Gambling at the University of Salford University, specialised in issues to do with games, to do the economic analysis. According to Toubon this Manchester-based institute specialised in gambling is financed by several gaming organizations. He asked the question: 'do you really believe that this institute can still be objective when it is financed by those you favour liberalisation?' He put the question of whether this is not a conflict of interests to the Commission, and received an answer from Commissioner McCreevy that this was not at all the case. Toubon still maintains that the Swiss institute amended the

85 Report, Committee on the Environment, Public Health and Food Safety, rapporteur Avril Doyle, PE 360.264/v02-00 A6-0301/2005, 13 October 2005.

86 Emphasis AM.

87 Newsletter from the European Parliament Legal Affairs Committee, Number 5/2005-6L, 21 April 2005. Http://www.europarl.eu.int/comparl/juri/newsletter/20050421.pdf (last accessed 15 July 2007).

study on a few points that seemed 'too favourable'.[88] It should be noted however that this study falls in the category of 'preparatory studies', to be distinguished from 'impact assessments' for which the European Commission takes full responsibility. Still, this anecdote illustrates how contracting experts to produce economic data as input in policy processes can easily be perceived as problematic exactly because of the unclear status of the various pre-legislative documents.

IA on amendments

IAs labelled as such

Pre-packaging. The example that is often presented as the first 'official' IA produced by the European Parliament is the IA on proposed amendments to the proposed directive on pre-packaging supervised by MEP Toubon and conducted in the context of the IMCO Committee. This IA is one of the case-studies of this thesis and detailed information can be found in chapter VII.

Batteries. The initial attempt to involve the European Parliament in the experiment with doing an IA of substantive amendments to the Directive on batteries and accumulators (in which the Council was also involved, see IV.3.4), failed, allegedly because of lack of resources.[89] In the second reading however, when it became clear during the debate that the Commission and the rapporteur disagreed on a crucial point, a request for on IA was put forward. MEP Caroline Jackson even invoked the Common Approach on the occasion:

> Secondly, the rapporteur is moving his Amendment 42, calling for bans on lead and cadmium in power tool batteries. We believe that any such moves need to comply in the first instance with the common approach to impact assessment, recently agreed between the Commission, Council and Parliament. In this instance, Parliament, at my instigation, asked outside experts to draw up an impact assessment, but this was itself limited in its scope. We need a full assessment of the social, environmental and economic impact of any such bans before we agree to introduce them. *Until we have that full assessment, it would be irresponsible to follow the rapporteur's lead, because we would be law-making in the dark.*[90]

An assessment on the common position was prepared before the vote in second reading. Because there was a framework contract already in place it took only four weeks to prepare the IA and the vote was postponed for that period.

Fourth daughter directive on clean air. One example is the Environment Committee, whose coordinators referred to 'the specific example that had already taken

88 Interview with MEP Toubon. Original statement in French; translation AM.
89 SEC(2003) 1343.
90 MEP Caroline Jackson, debate, 12 December 2005. Emphasis AM.

place within the committee on impact assessment of Mr Kronberger's amendments to the fourth daughter directive on clean air'.[91] When MEP Kronberger put forward amendments aiming at introducing binding limit values for concentrations of the respective pollutants in ambient air and proposing to set ambitious long-term objectives with a view to reaching a high level of protection for human health and the environment a request was made that 'certain of the Rapporteur's amendments be subject to a rapid impact assessment, a new possibility opened up by the Draft Inter-Institutional Agreement on Better Law Making'.[92] It was immediately acknowledged that this request would lead to the delay of the final adoption of the report and a request for postponement was granted. However when the study was delayed, those committee members who were in favour to vote immediately (claiming the results of the study were clear already anyway), including the Greens, won the day.[93]

IA-type studies (not labelled IA)

A number of IA-type report on alternatives considered by parliamentary committees are never published as full IAs. This can be because of the very technical nature of the studies (and of the amendments themselves) but the reason behind this can also be of a political nature. IA is associated with certain standards which the authors or the MEPs commissioning the studies do not feel they can uphold, especially when the time constraints of the legislative process are a problem.

Pyrotechnics. A good an example of such an 'IA' is the study on the Pyrotechnics proposal carried out by the Centre for European Policy Studies. Arlene McCarthy reported during the plenary debate 4 April 2006 '[o]n the pyrotechnics proposal we are conducting an impact assessment on amendments proposed by our rapporteur'.[94] However in the very end the IMCO Committee decided that the study, which covered the effects of amendments to the recital could

91 *Ibid*. Referring to the policy brief by Oosterhuis and Skinner, The Fourth Air Quality Daughter Directive: Impacts and consequences of mandatory limit values' of January 2004. The full reference to the fourth daughter directive on clean air is Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, OJ L 23, 26 January 2005, pp. 3–16.

92 ENVI news, Newsletter from the European Parliament Environment, Consumers and Public Health Committee, 1/2004, http://www.europarl.eu.int/comparl/envi/pdf/envinews/2004/200401_en.pdf (last accessed 15 July 2007).

93 Interview national official B.

94 European Parliament, Debate on Better Lawmaking, 4 April 2006, Strasbourg, http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20060404+ITEM-013+DOC+XML+V0//EN (last accessed 16 July 2007).

not be called 'impact assessment'. It now appears on the website as a 'briefing note'.[95]

EP IA not on amendments

'Pre-emptive strike'

There are no concrete examples of the European Parliament commanding a study even before the Commission's IA was published in order to have some ammunition in the debate. However, anecdotal evidence suggests that in the case of the proposal for the liberalisation of the spare parts market (which was all about drawing the line between intellectual property protection and free competition), the idea of commissioning an IA as a 'pre-emptive strike' was floated in the Parliament.

Background studies

Of course commissioning background studies on topics relevant to Commission proposals have been common practice in the European Parliament for a long time. The challenge is now how to upgrade those studies to 'IAs'. An example of a background study which is almost an IA is the broad economic analysis carried out for IMCO Committee in the context of the proposed Consumer Credit Directive.

Making use of the absence of an IA

Requests for IA

In the second reading on the proposal for a regulation of the European Parliament and of the Council on certain fluorinated greenhouse gases proposals for extending the list of prohibited gases had been made by the rapporteur.[96] MEP Linda McAvan (PSE) wrote in her written contribution to the legislative debate that 'we cannot support those amendments to the legislation which seek to impose bans on certain F-gases *without a proper impact assessment*'.[97] MEP Glyn Ford (PSE) concurred but pointed to the Commission as the institution that should conduct this IA:

> At this stage we should leave these further bans for assessment by the Commission as to the overall impact they would have on the economy and environment.[98]

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95 Http://www.europarl.europa.eu/comparl/imco/studies/0608_pyrotechnicarticles_briefingnote_en.pdf (last accessed 16 July 2007).

96 Report, Committee on the Environment, Public Health and Food Safety, rapporteur Avril Doyle, PE 360.264/v02-00 A6-0301/2005, 13 October 2005.

97 Emphasis AM.

98 Explanations of vote, Wednesday 26 October 2005, Strasbourg. Http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20051026+ITEM-013+DOC+XML+V0//LT (last accessed 15 July 2007).

'No IA' as trump

The Parliament may fear that IAs will be used to oppose legislation and its amendments specifically, but MEPs can also be witnessed to use IA (or lack thereof) to oppose Commission proposals. For instance, rapporteur Ieke van den Burg in her report on current state of integration of EU financial markets wrote that she

> [b]elieves that the principles of better regulation, as set out in the Commission's 2002 Better Regulation Action Plan, should be followed; in particular any future measures, which should be targeted at correcting specific market failures, should include a costbenefit analysis of non-legislative options for addressing the failure.[99]

Another example of how the European Parliament sometimes uses the absence of an IA as an argument to dismiss a proposal without judging it on its merits is when the European Parliament turned down a proposal on market access to port services for a second time. In the debate that took place MEP Roberts ZÎLE (UEN/LV) called the Commission proposal 'typical and usual' because 'it was presented without an impact assessment'.[100]

This use of impact assessment amounts to using them as trumps; any substantive consideration is 'trumped' by the overarching consideration of lack of impact assessment.[101] However, an argument can be made that the use of IAs as trumps is encouraged by the Commission by making the absence of an IA one of the criteria when screening legislative proposals for withdrawal (see III.5.1).

Waste. No specific IA was done for the proposed revision of the Waste Framework Directive.[102] On the Thematic Strategy on Waste of which the revision (later) became part, an IA was done. Caroline Jackson, as quoted in an article by Euractiv, said that 'the Commission (…) did not produce an impact assessment on this as it normally required to do'. Although the articles did not make this entirely clear this statement referred to Annex II only. In her draft report she writes as part of the justification for an amendment:

> Although there is a case for introducing energy efficiency targets here *the Commission's text is unsupported by any Impact Assessment*. Such an Assessment is much

99 EP report (A6-0087/2005) of 7 April 2005, Committee on Economic and Monetary Affairs, p. 5.

100 European Parliament press release, 'Parliament sinks port services proposals', 18 January 2006.

101 Ronald Dworkin has coined the term 'rights as trumps' in his book *Taking Rights Seriously* (London: Duckworth, 1977) to denote a typical property of rights, namely that they take precedence over other considerations. Similarly, the fact that an IA has been carried out can take precedence over other considerations, including political discretion in the legislative process.

102 COM(2005) 667 final.

> needed. We need to know the cost of conversion for existing plants – if conversion of existing plant to meet the proposed energy efficiency standards is possible.[103]

But even more interestingly she continues:

> The rapporteur's amendment shows how it is possible to modify the efficiency standards to allow more existing incinerators to qualify as recovery operations. *It too, if adopted in committee, will need an Impact Assessment*.[104]

And further on:

> Evidence from France suggests that out of a total of 85 existing plants, only 14 could satisfy the recovery criteria chosen. Before the Committee votes it needs to know more details of the impact of what is proposed. *It cannot be right that at a time when the air is thick with suggestions for making impact assessment more efficient, we should miss such an assessment out completely on this crucial aspect of the Directive*.[105]

A last example from environmental legislation: MEP Caroline Jackson in the debate on the draft Directive on packaging and packaging waste,[106] where there was an issue of the rapporteur (Corbey) proposing later starting dates than the Commission, namely those proposed by the new Member States:

> Second, are [the earlier dates] based on any cost impact assessment? There must be some additional cost between the dates that the new Member States wanted and the dates the Commission is proposing.[107]

This directive, was indeed not accompanied by an impact assessment. Adopted in March 2005 based on a Commission proposal from 2004[108] a BIA was made for the proposal but no full IA. Although 2004 was the first year in which the IA procedure became fully implemented, the selection of proposals that should undergo an IA was still based on certain substantive criteria (see III.3.1) – different from 2005 onwards when IA was required for all initiatives in the CLWP. However, the call for IA in this area seems not to have fallen on deaf

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103 Draft report on the proposal for a directive of the European Parliament and of the Council on waste (COM(2005)0667 – C6-0009/2006 – 2005/0281(COD)) Committee on the Environment, Public Health and Food Safety Rapporteur: Caroline Jackson, provisional 2005/0281(COD), 21 June 2006, p. 25 (justification for Amendment 38 of Annex II, point R 1, paragraph 2, indents 1 and 2). Emphasis AM.

104 EP draft report Jackson, p. 25. Emphasis AM.

105 *Ibid.*, p. 27.

106 Directive 2004/12/EC of the European Parliament and of the Council of 11 February 2004 amending Directive 94/62/EC on packaging and packaging waste, OJ L 46, 18 February 2004, pp. 26-31.

107 EP debate, 16 November 2004, Strasbourg.

108 COM(2004) 127 final.

ears. When the Commission presented a report[109] on on the implementation of this directive in December 2006 it was accompanied by a Staff Working Document containing not a full impact assessment – there is no such requirement for this item – but a '[d]etailed evaluation of the impacts of the Packaging and Packaging Waste Directive and options to strengthen prevention and reuse of packaging' in Annex II.[110]

Request for IA work

The following represents an overview of cases in which (members of) the Parliament have asked the Commission for an impact assessment.

There are insignificant examples which have got little to do with the strengthened impact assessment procedure, but more with older evaluation tools such as SIA (see III.5.2). An example is the question from MEP Salinas García, expressing worries regarding the increase in the Moroccan tomato quota, she asks whether the Commission is 'considering drawing up an impact assessment on the effects of the increased Moroccan quota on Community tomato-growing areas?'.[111] The Commission answered that no specific impact evaluation was needed as it would continue to monitor very attentively the state of the tomato market.

Asking for future impact assessments of revisions of legislation is another category. An example of this is the proposed amendment in the context of the revision of the Directive on Postal Services by the Committee on Employment and Social Affairs stating that '[a]ny proposal for a further step [towards market opening, AM] will be based on the findings of these reviews and impact assessments'[112] As a second example, in the debate on the exemption of small-scale public services from state aid rules (the famous Altmark case[113] of the ECJ left a need for clarity in this area) MEPs called for an extensive impact assessment before the rules were renewed.[114]

It has even almost become a standard practice for MEPs to add a sentence that a 'new proposal should duly take into consideration the results of an

109 European Commission, Report on Directive 94/62/EC on packaging and packaging waste and its impact on the environment, as well as on the functioning of the internal market, COM(2006) 767.

110 SEC(2006) 1579.

111 Written question no 93 by María Isabel Salinas García (H-0243/05) on 14 april 2005.

112 Opinion for the Committee on Regional Policy, Transport and Tourism on the proposal for a European Parliament and Council directive amending Directive 97/67/EC with regard to the further opening to competition of Community postal services (COM(2000) 319 – C5 0375 – 2000/0139(COD),Draftsman: Proinsias De Rossa) of 7 November 2000. Amendment of Recital 14.

113 *Altmark*, Case No. C-280/00 [2003] ECR I-7747.

114 European Parliament news report, 2 February 2005, http://www.europarl.eu.int/omk/sipade3?PUBREF=-//EP//TEXT+PRESS+NR-20050202-1+0+DOC+XML+V0//EN&L=EN&LEVEL=2&NAV=X&LSTDOC=N (last accessed 15 July 2007).

impact assessment'[115] to their contributions to legislative debates. For instance, in the context of the debate on the White Paper on services of general interest MEPs Elisabeth Schroedter, Jean Lambert and Sepp Kusstatscher included in their draft opinion a request to the Commission 'to carry out a thorough impact assessment of the principles set out in the Services Directive on SGIs'.[116]

IV.2.5 Synthesis

This survey of IA practice in the European Parliament indicates an increase in the use by MEPs of impact assessment as a means of holding the Commission accountable for its proposals and as a tool in exercising their informal 'parliamentary right to be informed'. However, practical constraints surface immediately when making an inventory of the practice of IA in the European Parliament so far and are often held responsible for the alleged 'invisibility'[117] of IAs in the political process. But the problem runs deeper. But from the interviews carried out with MEPs and assistants this constraint appears to crop up in a much earlier stage than the point where the Parliament is faced with the choice whether to do its own IA or not. IAs provided by the Commission are rarely read, sometimes not even by the rapporteur. Even those who have engaged in the debate on the inter-institutional design of IA and in the practice of scrutinising Commission IAs are not always aware of the possibility to do a parliamentary IA on substantive amendments in accordance with the Inter-Institutional Agreement on Better Lawmaking of 2003.

One thing that emerges clearly from this overview of IA practice in the European Parliament is the difference between IA as substantive argument and IA as procedural argument. The Common Approach can be seen as one big attempt to steer the Parliament away from using IA as a procedural argument. The evidence from the emerging practice is very anecdotal in nature but still strongly suggest that the following future view expressed by MEP Caroline Jackson was too optimistic, at least in the medium term:

> The consequence of all this is that impact assessments, and battles over their adequacy, accuracy and when they come into play, are new features in the land-

115 European Parliament daily notebook of 9 March 2005, 'Improved Generalised System of Preferences for developing countries' on the Report on the proposal for a Council regulation applying a scheme of generalised tariff preferences by Antolín Sánchez Presedo (PES, ES).

116 Amendments 1-17, Draft opinion, 21 February 2005 (PE 350.234v01-00 PE 355.381v01-00,). Proinsias De Rossa, White Paper on services of general interest (COM(2004)0374)). Amendment 5, Paragraph 3.

117 Mr John Cridland was quoted as saying: "I also think that within the political process that then ensues impact assessments are completely invisible and both the Parliament and the Council need to get on board with this."in the COM(2005) 98 final, p. 6.

> scape of EU environment law, starting really from this year. They are bound to change the emphasis and I suggest may alter the conclusions of our debates.[118]

Certainly, some IA-related requests from the Parliament to the Commission can be seen as part of a sabotage strategy, certainly given the limited appetite for objective analysis in most parliamentary committees. It is becoming increasingly clear that it is hard for Commission IA to have a substantive impact if the Parliament views IA mostly as a vehicle for criticising the procedural side of the lawmaking process.

The various references to impact assessment can be taken as a sign that the discourse is changing: across the spectrum it is politically more opportune to ask the Commission for an impact assessment than for regulation. The latter could be seen more easily as aiming to interfere with the Commission's right of initiative. Besides, in this era of deregulation, the concept of regulation has become tainted in the eyes of some, whereas impact assessment with its air of objective, scientific analysis is much harder to oppose. Apart from a few exceptions, the tendency of the European Parliament is not to come up with its own IA, showing how the analysis can be done better and how this new information leads to proposed changes in the proposal, but instead call for a new impact assessment by the Commission. In this request, the Parliament likes to specify what needs to be improved, for instance the inclusion of a certain group of stakeholders. Of course, there are a few exceptions, such as the pre-packaging IA (see VII.1) and it is very well possible that the new framework contracts will facilitate more IA work od this type within the Parliament.

What remains unclear is why the European Parliament is not more transparent or communicative about its considerable amount of dealings with IA so far. The Parliament is being criticized for not delivering on their commitments of the 2003 Inter-Institutional Agreement and yet the handful concrete examples of parliamentary use of IA remain well hidden in the communication with the other Institutions and stakeholders. The rapid impact assessments of the Environment Committee are very hard to find, listed on a page which sums up the external studies which the committee has commissioned. The same goes for the impact assessment on pack sizes (see case study VII.1). This lack of transparency may disappear now that the Common Approach to Impact Assessment states in paragraph 7 that the Institutions will publish their impact assessments through single portals for each Institution on the Europa website.

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118 Dr Caroline Jackson MEP: Speech to the National Society for Clean Air 10 December 2003, "Europe – still setting the environmental agenda?". Http://www.carolinejackson-mep.org.uk/page.php?pid=17 (last accessed 26 October 2006).

IV.3 IA IN THE COUNCIL OF MINISTERS

IV.3.1 Main issues of IA in Council

Negotiation culture

Although there are three co-legislators, these do not have an equal amount of influence and the Council is often presented as the 'main decision making body' of the EU. The half-yearly presidency system means that the emphasis is often on closing the deal, sometimes at the expense of the quality of the results. Accordingly, the way actors in Council view the Commission IA differs from the perspectives of Commission (legitimizing its proposals) and the European Parliament (providing substantive and procedural grounds for questioning Commission proposals). The Member States represented in the Council are mainly searching for the specific impacts for their own country and especially for arguments to bend the proposal in their favour.[119] Some of the interviews conducted suggest that officials attending working party meetings tend to be very focussed on the instructions they received from their governments, leading them to view the Commission IA at best as something they are entitled to ignore, at worst as something that distracts from their mandate. However, some have indicated that they view IA as a potentially very useful source of arguments for those who compose the mandate, even if specification of impacts per Member State is often lacking. MEP Caroline Jackson made an interesting prediction in that respect:

> [The Member States] will also be concerned that the easy adoption of expensive new laws by a Council that doesn't ask for impact assessments will lead to the creation of a new patchwork of non-implementation across Europe.[120]

Third Pillar IAs?

Whereas the European Parliament's amendments are at least out in the open, the Council's contributions to legislative proposals, let alone its 'Third Pillar' proposals, are often lacking transparency. In the words of the European Commission:

> While Parliament usually provided a justification for its amendments, anecdotal evidence suggests that this was rarely the case for Council's amendments. When

119 Outside the Council supporters of the view that IAs should mainly serve to facilitate implementation by fleshing out national impacts can be found too. MEP Caroline Jackson is one example (interview assistant MEP Jackson).

120 Dr Caroline Jackson MEP: Speech to the National Society for Clean Air 10 December 2003, "Europe – still setting the environmental agenda?". Http://www.carolinejackson-mep.org.uk/page.php?pid=17 (last accessed 26 October 2006).

> Member States exercised their right of initiative for police and judicial cooperation in criminal matters and made formal proposals, compliance with the principles of subsidiarity and proportionality was more often stated than demonstrated. A review of the contents of the most salient debates on the matter confirms established trends. More often than not, Parliament's amendments have called for broader EU action and argued that stronger instruments are required to guarantee success, while Council's amendments were asking to narrow down the scope of the action envisaged or adopt a lighter form of intervention. In most cases, the three institutions eventually managed to come to a common interpretation of subsidiarity and proportionality.[121]

A particularly pressing issue is that of the current absence of any requirement or commitment to conduct impact assessments on Third Pillar proposals, for which Member States share the right of initiative with the Commission (Article 34 TEU). The Commission and certain stakeholders have repeatedly called for such an obligation, but the Council so far is opposed, claiming that there is no basis for this in the Inter-Institutional Agreement of 2003. From an inter-institutional perspective the absence of a requirement to conduct IA can lead to a sense of inequality, an unfair advantage when using of third pillar, as expressed by the Commission in its 2002 Action Plan.

> By analogy with the obligations concerning the Commission's right of initiative set out in the Protocol on the application of the principles of subsidiarity and proportionality, the Commission feels that the Member States should also carry out consultations and impact assessments when they exercise their right of initiative and make legislative proposals under Title VI of the Treaty on European Union and Title IV of the Treaty establishing the European Communities.[122]

Ever since, the Commission has maintained that, as a matter of institutional equality, it considers it appropriate that '[i]n the area of Title VI of the TEU (police and judicial cooperation in criminal matters), proposals made by the Council/Member States should be accompanied by impact assessments'.[123] Recently it has even added to this the firm wording that '[u]nder the 2008 review of the 'Common Approach to Impact Assessment', the Commission expects that the institutions will agree to conduct impact assessments on Member State initiatives in the area of Title VI of the TEU (police and judicial cooperation in criminal matters).'[124] A review clause of the Common Approach indeed suggests that in the context of the review of the document in two years time, 'as appropriate, Council Impact Assessment on specific

121 COM(2005) 98 final, paras 17-18.
122 COM(2002) 278 final, pp. 17-18.
123 COM(2006) 689, p. 8.
124 *Ibid.*, p. 11.

initiatives presented by one or more Member States concerning their economic, environmental and social aspects' could be considered.[125]

It is not surprising then that the Commission would welcome an obligation to conduct impact assessments of Third Pillar initiatives, when it has stated elsewhere that 'compliance with the principles of subsidiarity and proportionality was more often stated than demonstrated.'[126] However, it seems very uncertain whether the Commission's expectation will be fulfilled on this point. The Member States' governments do not seem keen to take upon themselves any kind of obligation to carry out impact assessment, although the national parliaments may have different views (see also V.2.2). As an illustration, the British House of Lords in their Thirty-First Report on 'Ensuring Effective Regulation' submitted the following to the British government:

> At present there seems to be no requirement for Member State initiatives to include an impact assessment. We believe that all key proposals should be accompanied by an impact assessment whether these proposals are initiated by the Commission or Member States (under the Third Pillar) to ensure that all possible policy options have been assessed ex ante.

The UK government's reaction revealed that:

> The predominant view in the Council was that Member State initiatives under the third pillar should not systematically be covered by this commitment, as by their very nature, they may not have direct substantive economic, social and environmental impacts. In addition, many Member States, in the first instance, preferred to develop experience of impact assessment based on amendments. (…) The Government will consider its position on this issue in light of experience during the two year period.[127]

The argument that third pillar initiatives 'by their very nature' may not have 'direct substantive economic, social and environmental impacts' is a weak one, especially given the fact that the Council has never protested against IA being carried out by the Commission on JLS proposals.

The European Parliament has also taken a stance on the matter. The Lévai report on Better Regulation of September 2007

> [i]nsists that Member States provide an impact assessment for their initiatives in the area of police and judicial cooperation in criminal matters, pursuant to Article 34(2) of the EU Treaty; considers that Member States should commit themselves to recognising a real obligation in this respect.[128]

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125 Common Approach to Impact Assessment (2005), para. 19.
126 *Ibid.*
127 UK Government's Response to House of Lords 31st report (2005), appendix 1, para. 47.
128 EP Lévai report on Better Regulation (2007), para. 15.

IV.3.2 Discourse on IA in Council

Council formations on Better Regulation

From the very beginning the following three Council formations were the ones dealing with Better Regulation matters: the Competitiveness Council, the General Affairs Council and the Economic and Financial Affairs Council (ECOFIN). The General Affairs Council which deals among other things with institutional matters was the one involved in the negotiations on the Inter-Institutional Agreement on Better Lawmaking.[129] As for the Competitiveness Council and ECOFIN Council there is no fixed work division between them, although the latter tends to focus more on macro-economic issues whereas the former is more about micro-economic issues. As the Better Regulation strategy developed, other Council formations became involved with Better Regulation issues, most notably the Environment Council.[130] On the working group level there is the General Affairs Group reporting via COREPER II to the General Affairs and the ECOFIN Council and the Working Group on Competitiveness and Growth and the High Level Group on Competitiveness reporting via COREPER I to the Competitiveness Council.[131] The European Council dealt with Better Regulation on several occasions, the last time being the mid-term review of the Lisbon strategy.

The goal of IA

The German guide to EU impact assessment,[132] written to assist national civil servants to better use EU impact assessment in their work is very explicit about the purpose IAs can serve in Council:

> Commission IA offers the member states an additional foundation for formulating and examining their own negotiating positions. In the Commission's view, IA represents the attempt to ensure a greater degree of objectivity in its decisions. However, in Council negotiations, the IA constitutes a document used by the Commission to justify and support its own proposals. The member states can use the IA to critically examine the Commission proposal.

However the Guide goes on to place this opportunity in the light of the need for the Council to improves its own efforts in the area of ex ante assessments:

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129 EC working document 'who is doing what on BR' (2004).

130 This Council formation held a public debate on Better Regulation and environmental policy, 17 October 2005 in Luxembourg.

131 House of Lords 9th report (2005), p. 26.

132 German guide to EU impact assessment, May 2006, available at http://www.verwaltung-innovativ.de/Anlage/original_1060703/Guide-to-Impact-Assessment-in-the-EU.pdf (last acccessed 20 July 2007).

> Depending on the circumstances, however, they must be able to justify any opposition to the Commission IA, which requires careful examination and possible support from own studies/reports.

The Guide is also careful to emphasize that actors in Council should not superimpose their own standards on Commission IAs:

> In particular, Commission IAs should be measured against the Commission's own guidelines.

The UK Presidency Conclusions of December 2005 contains an Annex on Better Regulation. After welcoming the Commission's revised impact assessment system, including the commitment to prepare integrated impact assessments for all major legislative proposals and policy defining documents in its work programme, the Council comments on the substantive framework for Commission IAs:

> These assessments should include exploring a range of options, drawing on sectoral analyses where available, which could potentially meet the set objectives of a proposal, including non-legislative options and further harmonisation, as appropriate.[133]

But the other two Institutions are pressed to jump on board:

> It calls on the Council and the European Parliament to make full use of Commission impact assessments as a tool to inform political decision making and to implement the interinstitutional common approach to impact assessment.[134]

The Finnish Presidency's progress report on Better Regulation presented at the Competitiveness Council on 4-5 December 2006 is remarkably little intergovernmental about the goal of IA than is often the case by simply stating that:

> The aim of impact assessments (IAs) is to bring a broader knowledge base to the decisionmaking process.[135]

But the most high-level institutional discourse on Council IA, which precedes the German guide and the Common Approach, can be found in the Council conclusions themselves. The consecutive Council conclusions mentioning Better Regulation can be read as a repetitive stream of good intentions.

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133 Presidency Conclusions, Brussels European Council, 15/16 December 2005, cover note 15914/1/05. REV 1, Brussels, 30 January 2006.

134 *Ibid.*

135 *Ibid.*, para. 5, p. 4.

The Competitiveness Council adopted conclusions on Better Regulation in May 2004. These commit it to developing, in the context of the Inter-Institutional Agreement on Better Lawmaking, a "proposed approach in relation to impact assessments which may be carried out on substantive Council amendments to be piloted during 2004".[136] Subsequently, in the Conclusions of the November 2005 Competitiveness Council the Common Approach was welcomed and the Council committed itself to undertake to 'embed it into Council work on impact assessment'. It also reaffirmed

> its intention to carry out impact assessments on substantive Council amendments, to be determined by the appropriate Council preparatory bodies, to legislative proposals, with a view to developing best practice, in line with the commitment in the Inter-institutional Agreement on Better law-making, without prejudice to the legislator's capacity to propose amendments.[137]

In the Council conclusions of March 2007 the language is firmed up somewhat:

> The European Council stresses the need for the Council and the European Parliament to make greater use of impact assessments.[138]

The Council has also set a time frame for possible more rigorous measures in the field of Better Regulation:

> In spring 2008, the European Council will consider on the basis of a review by the Commission whether further action is needed, taking into account different options, including a group of independent experts to advise the institutions on their work towards Better Regulation.

The Council on Commission IA

The Council for its part has on occasion raised doubts about the reliability of data used in the Commission IA and about the issue of whether the Commission IA should be the prerogative of the Commission only (the 'comprehensive nature of Commission IA'). In their statement the Six Presidencies have suggested that 'the process of deciding which Commission proposals are subject to any impact assessment, should be agreed with Council annually.'[139] According to the same document there should also be 'a more formal quality control on extended impact assessments before a Commission proposal is pub-

136 Press release of the 2583rd Council Meeting, Competitiveness (Internal Market, Industry and Research), 9081/1/04 REV 1 Brussels, 17 and 18 May 2004, p. 7.
137 EC working document 'who is doing what on BR' (2004), p. 4.
138 Council conclusions (2007), para 23.
139 Six Presidencies Joint Statement (2004).

lished'.[140] This recommendation is along the same line of thinking as the audit function recommended by the Parliament (see IV.2.2).

IV.3.3 Procedures for IA in Council

Practical organization

The issue of how to make use of Commission IAs in debates on legislation is, just like in the European Parliament, still largely unresolved by the Council, but takes a more high-level profile[141] and is more precise and technical at the same time. For instance, the UK Presidency announced its resolve to seek to facilitate better use of Commission impact assessments to inform Council discussion.[142] Also, in a decision of 23 June 2004, the Permanent Representatives Committee (COREPER) concluded that the Council working groups should take IAs presented by the Commission into account in negotiations and report on this to COREPER.[143]

Whether or not the European Commission will be willing to assist the European Parliament or the Council with IAs on amendments is likely to depend on the Commission's perception of the nature of the proposed amendment. If an amendment is perceived to be meant only to delay the legislative process, the Commission will probably be unwilling to provide assistance. If on the other hand an amendment is undesirable in the eyes of the Commission, and it has data to show why, the Commission might be very willing to assist. A complicated situation may arise when a proposed amendment is to the liking of certain DGs and not others: with such an informal procedure DGs may use assisting with data or analysis as an alternative way of getting what they failed to achieve in the internal inter-service decision-making. An example of were the IA really intensified contact between Council and Commission is the case of the e-customs.[144] The Member States felt that the Commission had not illustrated the effects well enough and the negotiations even stopped, until the Commission returned with additional data.[145]

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140 *Ibid.*

141 For instance at the 17 October Environment Council a policy debate on how to use Better Regulation and Impact Assessment when deciding on the 'Thematic strategies' has taken place.

142 Better Regulation – Information note, 5 July 2005, http://register.consilium.eu.int/pdf/en/05/st10/st10862.en05.pdf (last accessed 15 July 2007).

143 German guide to EU impact assessment, May 2006, available at http://www.verwaltung-innovativ.de/Anlage/original_1060703/Guide-to-Impact-Assessment-in-the-EU.pdf (last acccessed 20 July 2007).

144 SEC(2006) 570.

145 Informal communication EU official.

Guidance for Working Party Chairs

After the Luxembourg Presidency already did preparatory work, the Austrians completed drafting the document 'Handling IAs in Council: Indicative guidance for Working Party Chairs' often known as the 'Austrian Handbook' in 2006. Subsequently the draft went to the Council Secretariat for comments, which resulted in a new draft. Some Member States such as Spain and France had some reservations, emphasizing the need to stay within the *acquis communautaire* and this is why the document is now called an 'indicative guide'. The draft guide was not sent separately to the Parliament and the Commission for comments, but the Commission was present at the Working Party meetings where it gave some comments. In this respect the drafting process of the 'Council guidelines on IA' differed from that of the Commission Guidelines, which was a purely internal affair. The Handbook received blessing from COREPER, subject to a few qualifications, for instance that it should be applied in an appropriate way.

The 'Austrian Handbook' represents the most ambitious effort so far to implement IA in the Council decision-making procedures. It is an important document, but not in the sense that it is being used all the time (on the contrary) but in the sense that it is a platform for continuing work. From this document and from the Common Approach some procedural rules for IA in Council – or to be precise: in Council Working Parties – can be distilled. These rules come in three categories:

- basic rules: guiding principles to be used for interpretative purposes or in the absence of specific rules;
- traffic rules: rules guiding the communication relating to IA between the three Institutions;
- procedural rules: rules touching on the internal decision-making procedures in Council.

On the use of Commission IAs the basic rule is that consideration of Commission IA not a separate exercise, but it should occur in the earliest stage of the discussion on the proposal in WPs (i.e. before the substance of a proposal is dealt with). The first traffic rule is that the Commission should be allowed to present the evidence. A second one is that in the end the Commission has 'ownership' of its IAs; the Presidency may at most, in the case of broad agreement among Member States, invite the Commission to update or amend the IA.

The procedural rules can be divided into two stages. In stage one a 'usefulness' check should be performed by the Working Party chairs on the basis of an initial checklist provided in the Handbook. This check is to be distinguished from any kind of quality review which takes place later in the process; instead the chair should simply look at whether the Commission IA is useful for the discussion of the IA that is to follow. The Handbook contains the following non-exhaustive list of potential 'omissions' in Commission IAs:

- lack of evidence of consultation and its use;
- potential options not covered;
- clear gaps in evidence;
- the 'balance of evidence' is not reflected in the chosen option;
- no adequate consideration of 'three pillars' or unclear legal impact;
- potential consequences for Small and Medium Enterprises (SMEs) not specifically addressed.

If an omission is found clarification should be asked from the Commission, on an informal basis. The discussion in the Working Party can be postponed if needed. The Chair should have a brief discussion on the IA with the Council Secretariat and the Commission at the pre-Working Party. Any concerns at this initial stage should be reported to COREPER.

Then in the second stage discussion of the substance of the IA is to follow in the Working Party. The Handbook even gives procedural rules on how to discuss the substance of a Commission IA in a Working Party. The key question should always be: 'does the IA provide sufficient information for a well-informed debate on the proposal?'. Furthermore delegations can challenge the information but the discussion should be structured around a Commission presentation and the Presidency prepares questions beforehand. In case further clarification from Commission is sought at this stage, the same rules apply as for the 'usefulness check'. The Handbook is even careful to mention that discussion of national impacts or national IAs may be appropriate. A summary of the discussion is to be sent to COREPER.

As for the second mode of use of IA in Council, the possibility of performing an IA on its own substantive amendments, the basic rules are rather elaborate. First of all, the Commission's impact assessment should always be the starting point for further work. Second, the Council has to organize and present, to the greatest possible extent, its impact assessments in a way that will ensure comparability with the Commission's impact assessment, without duplicating the Commission's work however. As a third basic rule it is, at least in first instance, for the Council to determine whether an amendment is 'substantive', but this decision should 'reflect the shared and balanced commitment to IA and Better Lawmaking in general'(Common Approach). A final basic rule is even more indeterminate: IA should not affect the Council's capacity to introduce amendments.

The traffic rules applicable to IAs on amendments are twofold. Firstly, the Commission will share any particular methodology used to prepare an impact assessment. Secondly, the Commission will also assist the Council and the European Parliament in their IA work by explaining its assessment and sharing the data used. (depending on the availability of Commission resources). As a matter of procedural rule the IA work is organized and coordinated by the Presidency, supported by the Council Secretariat. If the Working Party cannot agree on whether an amendment is 'substantive' that decision will be made

by COREPER on a proposal from the Presidency. Here too, any concerns during the process are to be reported to COREPER that also receives a report afterwards. The handbook stresses the 'flexible approach' the Council has to take on the delicate issue of who performs the 'Council IA'. Indeed, the possibilities are far more numerous than for Commission IAs due to the complicated institutional structure of the Council. The Working Party can opt for a 'Presidency IA', for an IA by external consultants or for an IA by the Council Secretariat. As a final option, the Commission can be invited to provide assistance.

IV.3.4 IA practice in the Council

> During its Presidency, Finland emphasized taking the principles and objectives of Better Regulation into practical legislative work. The Council's working groups consistently made sure that in the handling of the Commission's proposals impact assessments were also taken into account. In my opinion, we succeeded in this work very well.[146]

Scrutiny of Commission IAs

> [T]he Council will examine the Commission's IA alongside the Commission's initiative.[147]

The general impression is that the use of Commission IAs as information documents and the awareness of the importance of IAs more generally has increased across the Council. This impression, although certainly reinforced by informal talks with officials in Council,[148] is hard to verify because of the inaccessibility of documents reporting on Council decision-making. That is why the emerging tradition that Presidencies report on their 'Better Regulation experiences' is to be applauded.

Such a progress report by the British Presidency mentions 12 instances of Commission IAs that have been put on the agenda of Working Parties. The UK government has also named the Chemicals Regulation (REACH, see VI.1) and the Capital Requirements Directive as two examples of dossiers agreed

146 Mauri Pekkarinen, Minister of Trade and Industry, Finnish Ministry of Trade and Industry (2006), 3.

147 Common Approach to Impact Assessment (2005).

148 Also, in the course of 2005 the use of IA in Council increasingly was a topic at conferences on 'the Commission IA system' with representatives from the Council Secretariat assuring that IA was a top priority for the Council and that a system for Council IAs was being set up.

during the UK Presidency, where the final outcome was based on impact assessment.[149]

Empirical support for the impression of growing awareness also comes from the Finnish report which claims that during the Finnish Presidency, as of end October 2006, 24 Commission IAs have been examined, in relation to both legislative and non-legislative proposals, in 16 different Working Parties.[150] However:

> As a general observation, the Council is still engaged in a learning process as regards using Commission IAs. Some working parties have already made the use of Commission IAs as a standard part of their working methods, some working parties have handled IAs for the first time.[151]

The report also suggests that the quality of Commission IAs is important for the follow-up of the IA in Council (the word 'decisive' is even used). It is also suggested that the Working Parties on some occasions have gotten back to the Commission for additional information or clarifications, 'in order to extend the knowledge base and to facilitate debate on the proposal'.[152] The Finnish Presidency also reports a great variety among Working Party Chairs when it comes to their level of familiarity with IAs and the handbook prepared by the Austrian Presidency. One of the things that influenced the way Working Parties make use of Commission IAs in a negative way was misunderstanding on the part of the Working Party Chairs about the status of IA and the appropriate way of handling IA.[153] Another remarkable finding is that Working Party Chairs tend to find IAs prepared in legislative files or policy files with close link to future legislative proposals more useful than IAs on broad policy proposals.[154] Finally, the report suggests that obstacles to examining Commission IAs are often of a linguistic nature:

> The summaries of the main finding of IAs, produced by the Commission and translated into all Community languages have been useful and contributed to the examination of the IAs.[155]

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149 UK Government's Response to the House of Lords' Thirty-First Report on Ensuring Effective Regulation in the EU, Appendix 1. Http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeucom/157/15704.htm (last accessed 24 October 2006).

150 Finnish Presidency Report on Better Regulation presented at the Competitiveness Council on 4-5 December 2006, para. 6, p. 4.

151 *Ibid.*, para. 7, p. 4.

152 *Ibid.*, para. 9, p. 4.

153 Note by the Finnish Presidency on 'The use of Commission impact assessments and the state of play of the pending simplification of the regulatory environment', DS 758/06, Brussels, 24 October 2006, p. 4.

154 *Ibid.*

155 *Ibid.*, para. 10, p. 5.

IA on amendments

The Council carries out IAs:

> when [it] consider[s] this to be appropriate and necessary for the legislative process, prior to the adoption of any substantive amendment.[156]

However, this has only led to one proper example so far and this was an explicit pilot, which goes under the name of 'the Batteries experiment'.

The Batteries experiment

The Dutch Presidency was very keen to provide the first experience with Council IAs on substantive amendments. The original aim was to have a couple of pilot projects, but after a disappointing tour of various departments the Commission's proposal for a Directive on batteries and accumulators[157] became the choice for a pilot project. This proposal was deemed suitable because there was a clearly identifiable element for which the Presidency estimated it would be possible and desirable from the Dutch national perspective to subject to further impact assessment.[158] Already at the stage of assessment by the Commission the IA for the Batteries Directive had been politicized to a considerable degree with conflicting views within DG Environment and the results of the inter-service consultation leading to amendments to the IA. The policy problem at stake was that due to the improper disposal of used nickel-cadmium batteries and accumulators (NiCd batteries), large quantities of the highly poisonous heavy metal cadmium were being released into the environment. However the proposed solution presented by the Commission in November 2003 was deemed problematic both in technical and financial terms by some Member States.

The choice for the Batteries proposal was endorsed by COREPER on 20 July 2004[159] and the Working Party on the Environment (WPE) was made responsible for identifying appropriate amendments and carrying out an impact assessment. The experiment was conducted under the supervision of the Dutch Presidency but had support from the Council Secretariat. The Commission agreed to supply data that it had used in its own impact assessment.

156 Common Approach to Impact Assessment (2005).
157 COM(2003) 723 final, which proposed to amend Council Directive 91/157/EEC, as amended by Commission Directive 98/101/EC.
158 Interview national official B.
159 Doc. 15494/03 – COM(2003) 723 final.

It was agreed that the Commission's extended impact assessment[160] would be the starting point for the additional IA work by the Council.[161] The WPE identified two key questions:

- Should the use of NiCd batteries be restricted or not?
- Is the Commission's proposed system of monitoring the municipal waste stream practical and reasonable?

The Council IA concluded that the system of monitoring the municipal waste stream as proposed by the Commission was too expensive. It also called for a partial ban on NiCd batteries and did not endorse an expensive system for monitoring municipal waste. The amendments approved in Council reflected this outcome.[162]

The experiment evaluated

On one evaluation of this experiment it could be argued that it was a success because the IA showed that the Commission had actually missed the best option. It was also a positive experience in the sense that the IA was really used by delegations in the negotiations in the Council Working Group Environment, with some even making their position depend on whether the Council's final impact assessment would find that a partial ban on NiCd batteries would result in positive impacts on the environment, thus justifying the negative economic and social impacts.[163]

However the case also reveals a problem with the use of IA beyond the Working Party stage. As negotiations progressed it became increasingly difficult to distinguish between a 'real' IA objectively describing the impacts of possible decisions and a political document prepared by a Presidency eager to close the deal on its own terms. Although the content of the Council IA on

160 Doc. 15494/03 ADD 1 – SEC(2003) 1343.

161 In October 2004, WPE agreed to select the following amendments for the pilot project: the suggested addition to Article 4(1) of a partial cadmium ban; consequential amendments to certain definitions; and the consequential deletion of Article 6 (waste stream monitoring) and Article 13(1), second subparagraph (specific collection target for nickel-cadmium batteries). These amendments reflect a compromise suggestion that the Presidency tabled to try to find common ground as the co-legislator has different views as to whether a wider ban on hazardous substances was necessary.

162 The Council amendments were approved by the European Parliament in the first reading but not in the second when a new Parliament was in session. On 24 November 2004, the pilot project ended officially by a declaration of the EU Presidency. The reference to the adopted directive is Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (Text with EEA relevance), OJ L 266, 26 September 2006, pp. 1–14.

163 German guide to EU impact assessment, May 2006, available at http://www.verwaltung-innovativ.de/Anlage/original_1060703/Guide-to-Impact-Assessment-in-the-EU.pdf (last acccessed 20 July 2007).

the Batteries proposal was discussed in COREPER, lack of any framework of reference or other guiding norms led the chair to dismiss the IA as a relevant document in negotiations at some point.[164] It is entirely possible though that a more comprehensive Commission IA that included the options of the partial ban would have received a more willing ear at the COREPER level as the status of the document would not have given cause for confusion. On a more positive note the German Guide to EU impact assessment reports that:

> Carrying out the Council IA did not require any additional financial or personnel resources. The IA did not result in any substantial delay of the Council negotiations.

However, it should be remembered that the Dutch Presidency still had a few officials working on this for a couple of months. It agreed to do the pilot project because it really wanted to set an example and because this wish coincided with national interest in an IA that could steer the negotiations in the desired direction. In general this experiment does not give rise to much optimism when it comes to the incentives for Council Presidencies to engage in 'Presidency IAs', one of the options mentioned in the Council Guide for Working Party Chairs.

Other examples

The UK government has said that it will be 'encouraging both Institutions to fulfil the commitments they have signed up to, for example, by requesting impact assessments in the Council where we feel this would be appropriate'.[165] With that statement in mind the results of the UK Presidency seem rather meagre. Since using IA in the European legislative process was a priority for the UK Presidency, the Better Regulation Executive (BRE) set out to find suitable dossiers in which substantive amendments could be made on which IAs could then be made. But they had the same experience as the Dutch: even after asking responsible colleagues in all departments, this was quite difficult.[166] A Presidency paper about the progress on impact assessment reports two rather low-profile Council experiments, namely on the Potato Cyst Nematode Directive[167] and the Forest Law Enforcement, Governance and

164 Interview national official B.

165 UK Government's Response to the House of Lords' Thirty-First Report on Ensuring Effective Regulation in the EU, Appendix 1, para. 71. Http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeucom/157/15704.htm (last accessed 24 October 2006).

166 Informal communication national official.

167 Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC, OJ L 156, 16 June 2007, pp. 12–22.

Trade Regulation (FLEGT).[168] In both cases 'Council discussions and amendments to the original Commission proposal were informed by the Commission's extended impact assessment, supplemented by additional work by some member states'.[169] In one of those to cases, the one of the Potato Cyst Nematode Directive, the resulting report was not labelled as an IA. The reason for this could well have been that Commission had not done an IA on the proposal and that therefore the authors of the report perhaps thought it best to keep this file out of the IA context altogether.

'Mini-IAs' which hardly ever get labelled as 'impact assessments' are regularly conducted by Member States with developed evaluation cultures, such as the UK, the Netherlands and the Scandinavian Member States. If all Member States produced these 'mini-IAs' and the results were combined, the picture would probably differ greatly from the one painted in the Commission IAs.

A final illustration of the lack of IA activity on the part of the Council is the following inter-institutional episode. A question was asked by MEP Caroline Jackson about the plans of the Council to implement its duties under the Inter-Institutional Agreement on Better Lawmaking.[170] She specifically inquired if the Council was prepared to make the IA procedure a reality in the case of the draft directive revising the Bathing Water Directive[171] and the draft Directive on Battery Recycling.[172] In its answer the Presidency refers to the 'ongoing work under the Interinstitutional Agreement'.[173] It stated that the IA work on substantive amendments of the Batteries Directive was carried out during the second semester of 2004 with the support and guidance of the Dutch Presidency. Furthermore it confirmed that the Council's common position was formally adopted in July 2005 and that the Council did not foresee another impact assessment on this legislative proposal.[174]

168 Council Regulation (EC) No 2173/2005 of 20 December 2005 on the establishment of a FLEGT licensing scheme for imports of timber into the European Community, OJ L 347, 30 December 2005, pp. 1–6.

169 UK Government's Response to the House of Lords' Thirty-First Report on Ensuring Effective Regulation in the EU, Appendix 1, para. 66. Http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeucom/157/15704.htm (last accessed 24 October 2006)/.

170 Question no 36 by Caroline Jackson (H-0654/05).

171 Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC, OJ L 64, 4 March 2006, pp. 37–51.

172 Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (Text with EEA relevance), OJ L 266, 26 September 2006, pp. 1–14.

173 Which by now has resulted in the Common Approach.

174 "Concerning the draft Directive on bathing water which has reached the stage of conciliation, the Council does not envisage carrying out a specific Council impact assessment."

IV.3.5 Synthesis

The main problem with IA in the Council is broadly similar to that of the Parliament: there is no clear criterion to determine whether or not an IA should be done. This, combined with a lack of institutional incentive and a lack of resources to carry out IAs 'in-house' means that the practice of producing IAs is limited. Other problems are a lack of enthusiasm about IA, technical problems (how to go about it) and a widely shared hesitation about the added value. The overall picture emerging from interviews with national civil servants who go to Council Working Parties that they are mainly interested in carrying out IA because it provides arguments, not because it can challenge preordained positions. Finally, even if IA work is carried out at the Working Party level, it seems that the higher decision-making levels are reluctant to use the IA. A suggestion for avoiding this in the future is that COREPER or even the Council of Ministers could indicate the terms of reference for the IA beforehand. However, this could amount to a replacement of the political discussion: Member States are bound to disagree on which impacts merit further investigation and through which method.

IV.4 CONCLUDING REMARKS

> The Commission is the most committed of the three bodies to the action planned. The Parliament has some considerable distance to go. As far as the Council is concerned, I think there has been a mixed track record.[175]

A few years down the line this observation still rings true. Also, even after successive documents aimed at 'inter-institutionalisation', IA cannot be qualified as a shared substantive or procedural standard common to the three co-legislators. So far it seems that the Institutions have not managed to find common ground in the fact that they are all trapped in a situation they feel very ambivalently about.

Up until now there is no enforcement of inter-institutional obligations relating to IA. But a statement by Commissioner Verheugen at his examination by the European Union Committee of the House of Lords on 4 July 2005 suggests that the Commission does not exclude insisting on the production use of IAs for substantive amendments as a precondition for a legal basis for legislation in the future:

> If in the codecision process Parliament and/or Council produce amendments, changes which are not only just minor but real changes, then there should be an

175 Sir David Arculus as quoted in House of Lords 9th report (2005), 2 of the Minutes of Evidence.

> Impact Assessment. If it is not there the Commission will make it very clear that the Commission does not feel that there is a sound basis for a proper decision.[176]

This is some firm language indeed. However it seems unlikely that this threat of enforcement of the Inter-Institutional Agreement on Better Lawmaking and the Common Approach on Impact Assessment will get a sequel in court, as it is difficult to see what the incentive for the Commission could be to pursue such a course of action. The Action Plan also mentions that the Commission will withdraw proposals when amendments 'denature' the proposal, but this has so far never happened (at least not explicitly for this reason).

176 House of Lords 8th report (2005).

V EU IA beyond codecision

V.1 Involving co-actors

Regulatory debates are not confined to the three Institutions that were called 'co-legislators' in the previous chapters. And just like lawmaking never takes place in isolation from the wider institutional and social world outside the public institutions directly involved, IA cannot function in isolation either. This chapter explores the EU IA regime from the perspectives of different 'co-actors' with an acknowledged interest in the EU lawmaking process, but with varying degrees of access to it. Some of these co-actors are keen on IA playing a role in the legislative process whereas others are reluctant. All actors identified have a potential interest in or role to play in the outcome of the legislative process and who therefore can be referred to as 'co-actors' in the IA process. For most co-actors one or more of the following issues will be discussed:

1. their contribution to the debate on the development of the EU IA system;
2. the question of whether and how these actors can contribute to Commission IAs (or in exceptional cases even to IAs produced by European Parliament and Council);
3. the question of whether and how the co-actors can and do make use of IAs produced by the legislative Institutions (notably the Commission);
4. what scope there is for the co-actors to produce their own IAs and how that could contribute to the 'EU IA'.

V.2 National institutions

V.2.1 Member State governments

This section deals with Member States' involvement with EU IA as separate from their involvement in Council capacity, which was already discussed in section IV.3. If one takes the view that EU legislation should be drafted, from the very beginning of the process, with the value of variety and diversity in mind, it is only logical that the Member States should have a role to play in the ex ante assessment of that legislation.

The 2002 Action Plan included a paragraph on 'developing a common legislative culture within the Union' which mentioned exchanging 'good

practice such as legislative impact assessments'[1] as one way of achieving such a culture. More explicitly the Commission stated in the same communication that '[i]n order to improve the quality of national transposing measures, the Member States should establish consultation and impact assessment standards for any supplementary provisions added to legislative acts', in particular to avoid 'goldplating'. Furthermore the Commission expressed the view 'that the Member States should also carry out impact assessments on draft national laws which they notify to the Commission'.[2] These views were repeated in later Commission policy documents:

> Pursuant to the recommendations made by the Mandelkern group, the Commission expects the Member States to ensure that, whenever a national regulatory impact assessment is carried out, the results of that assessment are notified to the Commission and to the other Member States along with the details of the regulatory measures themselves.[3]

The latest Commission communication on Better Regulation identifies very clearly what the Commission expects from Member States in the field of IA, as part of a soft law requirement of the lightest kind:

> [m]ore systematic assessment of economic, social and environmental impacts through adequate guidelines and resources, and more transparency on the results.[4]

Some have even pleaded in favour of decentralising IAs on European legislative proposals to the Member States, since most of the costs and benefits of legislation are felt at the national level.[5] The European Parliament in its reaction to the 2002 Action Plan has also stated that it regretted the fact that in its Communication on impact assessment[6] the Commission has ignored 'the effects of the Community's legal acts on the Member States' existing administrative structures and procedures'.[7] The literature has mentioned "impact assessment of proposed EU legislation on the national legal systems in general' and added that '[i]n order to be effective and comprehensive this should be

1 COM(2002) 278 final, p. 18.
2 *Ibid.* Footnote 34 adds:"In accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 204 of 21.7.98 (modified by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998, OJ L 217 of 5.08.1998)".Presumably this is meant as an example of a requirement to notify national regulations.
3 COM(2001) 726, p. 3 and footnote 3.
4 COM(2006) 689, p. 3.
5 MEP Diez González at the European Parliament hearing where the Doorn report was discussed.
6 COM(2002) 276.
7 EP Draft Opinion Action Plan Better Lawmaking (2002), p. 4.

carried out not only at the European level but also at the national levels.'[8] The Doorn report also encourages Member States to exchange experiences in the use of impact assessment. Two main coordination mechanisms to this end are in place today: Directors and Experts of Better Regulation (DBR) and the High-Level Technical Group.

Directors and Experts of Better Regulation

In the context of the Directors and Experts of Better Regulation (DBR) senior national and Commission officials meet two to four times a year to coordinate and to further the initiatives on Better Regulation that can be taken by Member States as proposed by the Mandelkern report and the 2002 Action Plan. In a recent move to make the body more effective it has been decided to link the chair to the incoming Council Presidency. Unable to issue official documents, DBR takes action mainly through ad hoc actions which require the type of high-level, informal coordination that this body can offer. For instance, in the context of DBR, the initiative was taken to translate a number of national RIAs, leading to a comparative report containing an inventory of good practices and recommendations for the use of RIA by Member States.[9] Later on, the DBR-led Experiment with Ground Water Directive,[10] investigated in very concrete terms what role impact assessment can play in improving implementation of European law. Member States, even those without a proper IA system in place, were asked to make their own assessment of the proposal for a new Ground Water Directive. On the request of DBR the resulting IAs were compared by the Regulatory Policy Institute, who also wrote a report with recommendations.[11] Furthermore, and as mentioned in the Council guidance document on Handling IAs in Council, DBR has taken the initiative of starting up a pilot training event on multi-level impact assessment for national officials, hosted by the University of Exeter.[12] The main aim is to give national officials a practical understanding of the European Commission's approach to impact

8 Hirsch Ballin and Senden (2005), 157. It seems however that this remark does not necessarily refer to the actual IA system in place and seems to view it mostly as a matter for legal drafting experts.

9 Formez, *A Comparative Analysis of Regulatory Impact Assessment in Ten EU Countries. A Report prepared for the EU Directors of Better Regulation Group* (Dublin, 2004).

10 Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, OJ L 372, 27 December 2006, pp. 19–31.

11 Regulatory Policy Institute, *DBR Benchmarking Project: RIAs of the national effects of the proposed Groundwater Directive*, report for the Directors and Experts of Better Regulation (Oxford, 2005).

12 Editions of this training course took place at the Centre for Regulatory Governance of the University of Exeter between 24-27 July 2006 and 21-23 March 2007 and will run again between 10-12 September 2007.

assessment, the ways in which IA can be used in Council and by Member States on the national level and certain more technical aspects of IA.

High-level group of national experts on Better Regulation

On 28 February 2006 the Commission established a group of high-level national regulatory experts,[13] delivering on the commitment made in the March 2005 Communication and with the aim of facilitating 'the development of Better Regulation measures at both national and EU level'. After initial suggestions that this group would be involved in screening individual IAs – a task which is now allocated to the new Impact Assessment Board (see III.4) – the current constellation of the group discusses general Better Regulation policy and 'shall not give its opinions on initiatives or projects concerning the development of specific legislative proposals'.[14] There is a substantial overlap with DBR in terms of the persons attending the meetings of both groups. This high-level group is convened by the European Commission's Secretariat-General, instead of by the EU Presidency, as is the case with DBR. The minutes of the high-level group are publicly available from a special page of the DG Enterprise website.[15]

National IAs on EC legislation

National IAs on European proposals can be used in two distinct ways: for European purposes (by providing information that can be used in negotiations with the other Institutions) and for domestic purposes (implementation can be facilitated by anticipating the effects of a proposals). With the former category it is difficult to envisage IA functioning as an objective tool informing both policy-makers and the public as these documents will a) often not be public and b) contain arguments rather than 'information'.

The United Kingdom is widely seen as the frontrunner when it comes to development of regulatory impact assessment in general. More particularly it has integrated the use of this instrument into its standard procedure for negotiating European legislation. The UK government in the 'Transposition Guide' on 'how to implement European directives effectively' recommends to its civil servants that '[a]n RIA can be very effective as a tool, both to inform the negotiation and the transposition of a European directive'.[16] Further on the following piece of advice is given:

13 OJ L 76/3, 15 March 2006.
14 *Ibid.*, para. 2 of the recital.
15 Http://ec.europa.eu/enterprise/regulation/better_regulation/high_level_group.htm.
16 Cabinet Office, Regulatory Impact Unit, 'Transposition guide: how to implement European directives effectively?', 3. This guide is also referred to in other countries, see e.g. http://www.europadecentraal.nl/emc.asp?pageId=1134 (last accessed 15 July 2007).

> Use your RIA as a basis for discussion with the Commission, other Member States and the European Parliament before and during the negotiations. Be prepared to contribute information from your own RIA into the Commission's impact assessments and its consultation exercises.[17]

The Transposition guide also reports a successful case of using national IAs for negotiating purposes:

> A good example of how RIAs can be an effective tool in shaping proposals at an early stage was a European Commission proposal to set new emissions limits for vehicles undergoing a roadworthiness test (MoT test). The UK RIA was made available to other Member States and the Commission just before formal negotiations began. It demonstrated that the proposal had many practical weaknesses, including that the proposed limit values were not suitable for the timescale, and could in fact result in vehicles incorrectly failing the test. There was support for change in the light of this evidence and the Commission withdrew the proposal.[18]

Other cases of European proposals for which the UK government has undertaken a Regulatory Impact Assessment (RIA) are the Thematic Strategy on Waste[19] and the revision of the Waste Framework Directive.[20]

The German government in May 2006 produced a specific 'Guide to Impact Assessment in the European Union', which for the sake of 'EU-wide' transparency has been published in English as well. The chapter on 'Recommendations for action within the relevant ministry divisions' starts out with the following piece of advice:

> The quality and usefulness of IAs depend not only on Commission measures, but also on the active participation of Germany and other Member States. In order to ensure that German interests are effectively taken into account, it is important to assist the Commission in carrying out IAs and to keep a critical eye on the process from the very beginning. (…) By remaining aware of/participating in IA, Germany can also influence Commission proposals from an early stage, depending on the circumstances. In particular, it is important to clarify the possible impacts of a planned proposal on German interests.[21]

17 *Ibid.*, p. 4.
18 *Ibid.*, p. 8.
19 COM(2005) 666 final.
20 Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste, OJ L 114, 27 April 2006, pp. 9–21.
21 German administration, 'Guide to Impact Assessment in the European Union', May 2006, 20

And the advice becomes very specific on the next page:

> Attention should be paid in particular to the following:
> · checking the roadmaps to make sure they are complete/accurate with regard to the possible impacts on Germany;
> · if likely economic, social or environmental impacts on Germany have not been taken into account, the Commission must be informed of this without delay.[22]

To what extent Member States contribute to EU IA in practice is still a bit unclear, but the two documents discussed above represent a definite shift in approach on the part of Member States.

An Anglo-Saxon template?

Despite of the different conditions and starting points of national legislatures, IA is turning more and more into a common discourse among Member States. An interesting suggestion in this respect is that IA should be thought of as a 'European issue' and data should be readily made available by Member States who are more advanced in the technicalities of impact assessment.[23] Beyond the level of discourse though it is still unclear what they want from their Better Regulation activities'.[24] Attitudes in Member States vary from a reluctance to introduce IA (e.g. Hungary) to using the Commission guidelines as an example when developing national guidelines (Poland).[25]

An interesting phenomenon is that some Member States who tick all the boxes in self-assessment questionnaires on regulatory reform by the OECD, do not have any tangible 'impact assessments' to justify presenting their 'regulatory quality systems' as including impact assessments. An example is the Netherlands where a series of tests is carried out on legislative proposal but there is no 'master document' that reports on the impact assessment process and results. Instead, the idea is that the findings are summarised in the explanatory memorandum, in accordance with the requirements of the Legislative Drafting Guidelines and other (inter-)departmental guidelines. There are two possible takes on this situation. One could say that countries such as the Netherlands simply do not have impact assessment in any formal sense but that apparently they have found a clever way to jump on the wagon of Better Regulation discourse. Or one could argue that impact assessment – even as promoted by the European Commission – is an essentially Anglo-Saxon concept that simply does not fit with the institutional context of most 'continental' lawmaking processes, leading countries such as the Netherlands to adopt their

22 *Ibid.*, p. 21.
23 Informal communication national civil servant.
24 Radaelli (2007), 193.
25 EVIA country report (unpublished paper).

own version of impact assessment. Not only is the Anglo-Saxon IA template the most dominant one; when it comes to the debate on EU Better Regulation policy Anglo-Saxon voices are also the most present as illustrated by this statement from the British government:

> The Government agrees that the Commission's roadmaps are an important step forward in providing information at an early stage on its thinking in relation to overcoming policy problems. It is encouraging that the road maps for proposals in the Commission's 2006 work programme were published in November 2005. However, at present, the function of roadmaps is to indicate how the full impact assessment will be carried out—e.g. the options which will be considered and the Commission's plans for stakeholder consultation. In line with the views expressed by business representatives at our Presidency conference in Edinburgh, the Government would like to see the Commission communicate at an earlier stage to stakeholders the areas where it is considering action.[26]

V.2.2 National parliaments

Intensified involvement of national parliaments in European lawmaking is often put forward as an innovation that would enhance the legitimacy of the outcomes of legislative decision-making at the European level.[27] In the aftermath of the demise of the draft Constitutional Treaty in its original form, some national parliaments decided to intensify their scrutiny of European draft legislation outside of the explicit constitutional framework.[28] Now that the new draft reform Treaty proposes to restore the original idea of formalising the involvement of national parliaments in ex ante scrutiny for subsidiarity

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26 UK Government's Response to the House of Lords' Thirty-First Report on Ensuring Effective Regulation in the EU, appendix 1, para. 46. Http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeucom/157/15704.htm (last accessed 24 October 2006).

27 For a critical view on this suggestion, identifying "a series of misconceptions regarding the nature, function and capacities of the national parliaments" that has implications for the debate on their role in the EU constitutional system, see Kiiver (2005), 175. For an example of a plea in the media in favour of enhanced influence of national parliaments, see John van Lissa, 'Den Haag moet Brussel incorporeren', *NRC Handelsblad*, 28 November 2005.

28 An example is the Temporary Committee Subsidiarity Testing (*Tijdelijke Commissie Subsidiariteitstoets*) of the Dutch Parliament which has scrutinised 11 Commission proposals for compliance with subsidiarity and proportionality for the period of one year (March 2006 – March 2007). The committee, which is a joint body of the First and Second Chambers, will in all likelihood be continued as a permanent institution.

and proportionality,[29] the informal experiences of the past years merit extra attention.

A particularly interesting experience consisted of a joint initiative: the Conference of Community and European Affairs Committees of Parliaments of the European Union (COSAC) has acted as the forum for exchanging best practices and even undertaking pilot scrutiny exercises,[30] with backing from the European Council.[31] Subsidiarity scrutiny is a matter of national constitutional law but it is also dependent on the tools offered by EU institutions, enabling this early involvement. The Commission cooperated with the initiative by deciding to directly transmit Commission proposals (COM documents) with an invitation to react, from 1 September 2006 onwards.[32] This procedure provides an institutional structure to facilitate the Commission and the national parliaments entering into a dialogue about when (proportionality) and how (subsidiarity) the EU should legislate.[33]

Since IA is one of the main tools for implementing subsidiarity in the EU legislative practice, the relationship between IA and the subsidiarity initiative of the national parliaments merits a closer look. For instance, subsidiarity judgments by national parliaments could be made on the basis of the subsidiarity analysis in the IA. This is what happened in practice in COSAC's subsidiarity and proportionality check of the Commission proposal on 'matrimonial matters'. The national parliaments referred extensively to the Commission's impact assessment in their reactions, often even to specific findings. On the whole the references were positive, with the exception of the Lithuanian *Seimas* reporting that the main difficulty during the examination was a lack of any translation into Lithuanian of the full impact assessment[34] and the Czech Chamber of Deputies apparently unconvinced by the IA:

> The Commission's intervention into this area should be subjected to very detailed and accurate reasoning and justification. But neither the explanatory memorandum

29 Draft Treaty amending the Treaty on European Union and the Treaty establishing the European Community, version submitted to the Intergovernmental Conference (Foreign Ministers) meeting in Luxembourg of 15 October 2007, available at http://www.consilium.europa.eu/uedocs/cmsUpload/cg00001re01en.pdf (last accessed on 5 October 2007), Article 8c.

30 Two collective subsidiarity and proportionality checks were conducted by COSAC. The first was on the Commission proposal on jurisdiction and applicable law in matrimonial matters (COM(2006) 399 final) and the second on the Commission proposal on the liberalisation of postal services (COM(2006) 594 final).

31 European Council Conclusions, Brussels, 15-16 June 2006, http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/ec/90111.pdf (last accessed 17 July 2007).

32 Commission's Communication "A Citizens' Agenda" of 10 May 2006 COM(2006) 211 final

33 I. Cooper, 'The Watchdogs of Subsidiarity: National Parliaments and the Logic of Arguing in the EU' (2006) 44 *Journal of Common Market Studies*, 281-304.

34 COSAC, Report subsidiarity and proportionality check 'matrimonial matters' (2006), p. 14. Http://www.cosac.eu/en/info/earlywarning/doc/results/ (last accessed 17 July 2007).

> nor the impact assessment to the proposal removes doubts the necessity of a Community legal instrument regulating such conflict-of-law rules.[35]

For the other experimental COSAC subsidiarity and proportionality check, on 'postal services', it was less clear whether the Commission impact assessment played any role, with the national parliaments' reactions only containing passing references to IA, such as the Greek parliament mentioning that they had been sent the IA summary.[36]

Those who have expressed concerns over the current arrangements (warning for instance against clashes between the parliamentary scrutiny and the negotiation position of the government of the same Member State) and pleaded for an even earlier involvement from national parliaments,[37] may prefer to see the order of the procedure the other way around. In theory, the assessments by national parliaments – for instance on the basis of Roadmaps – could also serve as input for the Commission IA. This arrangement, however, would compromise the role of IA as an instrument for deciding whether to go ahead with a proposal or not, as national parliaments need a concrete proposal to base their assessments on.

Others have made a link with the importance of the European Parliament conducting IAs on substantive amendments: what is the point of scrutiny of legislation by national parliaments at an early stage if what they get to see is not what eventually emerges from Council, to paraphrase Lord Grenfell?[38] The implicit assumption here is that the obligation to conduct impact assessments will restrain the European Parliament in the exercise of its right of amendment. The logical implication of this view is that it is illegitimate – from an intergovernmental perspective – for the European Parliament to change legislative proposals too much, because this will diminish the influence of national parliaments. This kind of reasoning comes very close to the side-effects of introducing IA feared by the European Parliament when it initially resisted the development of a Better Regulation strategy.

A practical example of how national parliaments can use IA as a phenomenon for increasing their influence on European legislative decision-making outside the specific context of subsidiarity testing, comes – once again – from the British context. When debating the development of European private law

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35 COSAC, Annex to the report subsidiarity and proportionality check 'matrimonial matters' (2006), p. 25. Http://www.cosac.eu/en/info/earlywarning/doc/results/ (last accessed 17 July 2007).

36 COSAC, Annex to the report subsidiarity and proportionality check 'postal services' (2007). See http://www.cosac.eu/upload/application/pdf/b078b980/compilation%20of%20answers.pdf (last accessed 17 July 2007).

37 B. Steunenberg and W.J.M. Voermans, 'Subsidiariteitstoets is symbolische geste' (2005) (243) *Staatscourant*, 7.

38 Statement made at the Conference 'Sharing Power in Europe', 17 November 2005, The Hague.

the House of Lords sub-committee on Law and Institutions expressed its hesitations regarding the so-called 'optional instrument' (i.e. 'the establishment of a set of rules which would either apply automatically to cross-border contracts unless the parties ruled otherwise or would only apply if agreed by the parties') by stating:

> [w]e believe, and the Commission accepts, that an extensive impact assessment needs to be undertaken before any further work is undertaken on the optimal instrument.[39]

The sub-committee already has an objective for that IA in mind: 'that assessment should seek to determine whether an optional instrument would have a real effect on reducing cross-border transaction costs'. This way of referring to impact assessment as a prerequisite for further legislative action can be interpreted as is a way of expressing opposition to a proposal.

V.3 ADVISORY BODIES

According to the Commission's IA guidelines (see III.1.3):

> [O]rganizations such as the European Economic and Social Committee, the Committee of the Regions and the 'Ongoing and systematic policy dialogue with local-government associations' will often be able to provide useful information on impacts.[40]

But the official advisory bodies as established by the Treaty (Article 257 TEC and Article 263 TEC) would like to have a more structural and formalised role in the IA procedure. Their involvement in IA as well as their contributions to the debate will be discussed below, first in great detail for the Committee of the Regions and then more scantily for the European Economic and Social Committee.

V.3.1 Committee of the Regions

Role in the legislative process

The Committee of the Regions is consulted by the EU Institutions on matters that directly affect the responsibilities of local or regional government. The

39 House of Lords, Sub-committee on "Law and Institutions" of the Select Committee on European Affairs, *European Contract law – the way forward?*, 5 April 2005, p. 114.

40 SEC(2005) 791, p. 37.

Committee of the Regions has a comprehensive policy mandate, as the Treaty specifies that it must be consulted across ten broad policy areas. Furthermore, the Committee of the Regions can adopt opinions and submit them to the EU institutions on its own initiative. The argument commonly put forward to support a (greater) role for local and regional authorities in the development of new EU laws, is that an important part of EU legislation is implemented at local or regional level and therefore many impacts will be felt there. The potential link between impact assessment of European legislative proposals and the work of the Committee of the Regions is thus evident.

How to best fit in the contributions of the Committee of the Regions into the existing IA procedure, taking into account the existing agreement between the Commission and the Committee of the Regions on their cooperation, is far less evident. The 2001 Protocol concerning the relationship between the Commission and the Committee of the Regions extended cooperation between the two bodies beyond the strict scope set out in the Treaties. The Commission President now meets with the Committee of the Regions President each year to review political priorities and opportunities for cooperation, and presents the annual Commission work plan. According to the Protocol the Commission forwards to the Committee of the Regions, on the basis of the Work Programme, a list of proposals for mandatory consultation, along with proposals for possible optional consultation. The Protocol has also enhanced the Committee of the Regions' opportunity to influence legislative proposals through 'outlook reports' and 'outlook opinions' which the Committee of the Regions can make on an issue before the Commission develops a proposal. A new Protocol on the Cooperation Arrangement with the Commission was negotiated in 2005 and this was seen by the Committee of the Regions as an opportunity to specify the Committee's role in the IA procedure.

Role in EU IA?

The Committee of the Regions has been rather active in debating the new IA procedure.[41] It has expressed the hope that the partnership between the Commission and the Committee of the Regions in the process of drafting and implementing Community policies would lead to an 'increasingly systematic use of the new impact assessment method for the European Commission's major initiatives, and its involvement in the impact assessment method'.[42]

41 For example, the Commission for Constitutional Affairs and European Governance of the Committee for the Regions organized a seminar entitled 'Regional governance: a challenge for the efficiency and democracy of the European Union' on 13 May 2005 at which 'the institutions' obligations under the agreement on Better lawmaking' and 'the initiatives taken or planned by the Committee of the Regions to improve its ability to produce impact analyses' were discussed.

42 Resolution of the Committee of the Regions on the European Commission's Work Programme and the Committee of the Regions' Priorities for 2006, Brussels, 23 November 2005.

But what would that involvement look like? An obvious implication of the new IA procedure would be that the new IA Roadmaps will make it easier to identify the appropriate proposals for consultation on the basis that they need a more profound analysis of regional impacts. However the Committee of the Regions envisages a more active role for itself in the IA procedure, as it already hinted in its 'Impact Assessment report 2004':

> The development of methodological expertise in local and regional impact assessment would not only be beneficial for the relations with the Commission but also be interesting for the Council and the European Parliament. The three institutions agreed in the framework of follow-up activities to the inter-institutional agreement of 2003 'Better lawmaking' among other issues on the positive contribution of impact assessments in improving the quality of Community legislation: *'The institutions consider that improvement of the pre-legislative consultation process and more frequent use of impact assessments (both ex ante and ex post) will help towards this objective.'* The Council is for example currently evaluating the pilot project of an impact assessment. There is also a firm will of the Council, the Parliament and the Commission to discuss the impact assessments undertaken by the Commission in a more systematic way. The Committee of the Regions should therefore react in its Annual programming not only to the Working Programme in general but also point to a very limited number of Extended Impact Assessment procedures where a local and regional dimension would be beneficial.[43]

And in 2005 the Committee came up with a more specific wish list:

> The Committee of the Regions
> 2.3.1 PROPOSES that the introduction of a *new impact assessment method* for the *European Commission*'s major initiatives should lead to the local and regional dimension being taken into account to the greatest possible extent in the *ex ante* phase of the legislative process;
> 2.3.2 ASKS the *European Commission* to entrust it with drawing up *prospective analyses* falling within its remit, and, in particular, all major initiatives with a territorial impact;
> 2.3.3 CONSIDERS that a preliminary assessment on its part would be particularly important in terms of the application of non-regulatory instruments (*co-regulation* and *self-regulation*) and all *information* and *coordination* activities carried out at local and regional level;
> 2.3.4 BELIEVES THAT impact assessments must play a substantial role in *reducing the administrative burdens* of EU legislation on local and regional authorities and that, consequently, *preliminary assessments* must include an impact assessment of legislative acts at local and regional level, in *financial terms*;

43 CoR IA report (2004), 42. Emphasis in original. This is a report on the impact that the activities of the Committee of the Regions have made on EU policies rather than an IA in the sense of an ex ante assessment of a particular policy.

> 2.3.5 RECOMMENDS that in reviewing the protocol for cooperation signed with the *European Commission*14, the *extended impact assessments* should be used in order to define *detailed evaluation and quality criteria* for those who are to carry them out, and in order to establish a real strategy for consulting the grass roots at regional and local level;
> 2.3.6 INVITES the *European Commission* to foster a more proactive role in the pre-legislative phase of Community action in the form of *outlook opinions* on future Community policies, which would focus on the *impact* on local and regional authorities, and in the form of *reports* on the local and regional impact of certain directives;
> 2.3.7 RENEWS its recommendation to the *European Commission* to create an independent expert advisory group to monitor impact assessments, assure objectivity and encourage good practice, and to keep it briefed on its work so it can strengthen its the political role during later phases of the decision-making process;
> 2.3.8 ASKS to be informed of the progress of the *working group* on *managing and monitoring impact assessments* that was created within the *European Parliament*, so that it can take part in the *interinstitutional cooperation* group which was set up by the *European Parliament* and, with the help of the European Commission and the Council, develop a set of *common criteria* to evaluate the quality of impact assessments and quantify the costs arising from legislative proposals.[44]

Perhaps the most remarkable item on this list is the request to the Commission to entrust the Committee with drawing up 'prospective analyses', for all major initiatives with a territorial impact in particular. This implies a more formal role in the Commission's IA procedure. For the Committee of the Regions a privileged access to the Commission's IA procedure in an early stage could be a way of enhancing its influence on the process of policy development.

State of play

The Commission has always insisted it wants to remain responsible for carrying out its own IAs and for monitoring the quality of its own impact assessments (on the basis of the internal Commission IA Guidelines).[45] From that perspective, granting the Committee of the Regions a special role in the IA procedure represents an institutional risk as it potentially opens the door also to other actors discussed in this chapter. Extending an organization's role in the IA process beyond mere contributions through the regular consultation procedure, could be seen as the first step towards a formal role, entailing the power to influence the final content of the IA. Furthermore the argument can be made that the general use of consultation in the IA procedure already provides the Committee of the Regions with sufficient opportunities to make contributions on local, regional and territorial impacts as well as on specific

44 CoR report on Better Regulation for Growth and Jobs (2005), pp. 8-9. Emphasis in original.
45 SEC(2005) 791.

administrative costs for local and regional authorities and that it should simply start taking systematically advantage of these opportunities.[46]

The tension here is that the Commission consultation process which is supposed to interact with the IA process on the one hand relies on pluralistic assumptions of equality among all possible stakeholders. The establishment of special advisory committees on the other hand is an expression of the neo-corporatist conviction that certain stakeholders representing certain societal spheres (civil society or local governments) deserve a special ear in the legislative process. A procedure like IA, which is – on most accounts anyway – a means of translating stakeholder policy preferences into policy proposals brings this tension to the fore.

The final text of the 2005 Protocol contains little wording on IA and what is there has been phrased most cautiously:

> the Commission may ask the Committee to become involved (a) in studies pertaining to the impact of certain proposals on the local and regional authorities and (b) in exceptional cases, downstream, in the local and regional impact reports on certain directives.[47]

Subsidiarity and proportionality testing as a special angle?

> As regards political monitoring of the Union's legislative process, the Committee of the Regions has recognised, in the great majority of its opinions, the legitimacy of Union action. However in two cases it invited the European Commission to reconsider its choice of instruments in order to comply more faithfully with the proportionality principle. These recommendations have culminated in an approach that provides for the closer involvement of local and regional authorities in implementing Community legislation. Besides, the Committee of the Regions has announced that it intends to systematise its assessment of compliance with the subsidiarity principle in 2005 by preparing a subsidiarity evaluation grid annexed to its opinions and, on the other hand, progressively to create a network of local and regional authorities with a view to monitoring subsidiarity.[48]

Although this passage makes it clear that proportionality testing should not be underestimated, the Committee of the Regions recently has been most active in developing 'subsidiarity testing', following what can be called an institutional hype (see V.2.2 on subsidiarity testing by the national parliaments). Since subsidiarity is one of the core values addressed by IA, this could well be an important bridge to the IA procedure. This is recognised by the Committee

46 D. Scott, 'The (Missing) Regional Dimension to the Lisbon Process', paper delivered to the conference 'Delivering Lisbon: The Regional Dimension', 13 September 2005 (Brussels, 2005), p. 11.

47 Protocol on the Cooperation Arrangements between the European Commission and the Committee of the Regions, 17 November 2005, para. 3.

48 COM(2005) 98 final, p. 7.

of the Regions when it puts forward the concept of what could be dubbed 'preventive consultation':

> WELCOMES the priority strategic objective that the European Commission has set itself concerning the 'Better lawmaking' action and the inter-institutional cooperation initiated on the issue; REGRETS, however, that the local and regional dimension has not been adequately recognised in this initiative and URGES the presidencies of the Council, the European Parliament and the Commission to involve it more closely; also REGRETS that the European Commission in its annual planning document *does not consider the added value provided by a preventive consultation of local and regional governments regarding respect of subsidiarity.*[49]

In its subsidiarity analysis sheet of the Subsidiarity Monitoring Network of the Committee of the Regions some questions on IA are included:

> 13.1 Has an impact assessment been made?
> 13.2 If yes, is it comprehensive?
> 13.3 Were regional/local aspects taken into account in the impact assessment?
> 13.4 Has the Commission produced a separate subsidiarity assessment that also takes into account regional and local authorities?[50]

However, the implications of negative answers regarding the impact assessment as part of subsidiarity monitoring remain unclear for the moment.

V.3.2 European Economic and Social Committee

Since the general debate on IA involvement of the European Economic and Social Committee (EESC) is very similar to that on the Committee of the Regions, this section is rather brief. The Commission has pointed out that

> [t]he need for Better Regulation was also emphasised by the European Economic and Social Committee. At its September plenary session the Committee considered that this was a real 'social requirement' demanding intense interinstitutional involvement with a high degree of participation on the part of organized civil society as well. It also called for a 'cultural' change with greater emphasis on effective enforcement rather than the bringing in of new European laws.[51]

The EESC has produced two opinions on Better Regulation. Next to the opinion by rapporteur Van Iersel on the specific subject of 'Better Implementation of EU Legislation', there is an 'exploratory opinion' on 'Better lawmaking' by

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49 CoR resolution on the Commission's Work Programme (2005). Emphasis AM.
50 Http://www.cor.europa.eu/document/activities/Subsigrid.pdf (last accessed 15 July 2007).
51 SEC(2005) 1200 final.

rapporteur Retureau, written on request of the UK Presidency.[52] The opinion contains a number of interesting suggestions. It proposes that Commission impact assessments 'assesses how the legislation can actually be received, how it fits in with the existing body of law, and any potential implementation difficulties',[53] a very Member State-friendly take on the matter. The Committee expressed itself on the subject of the desirability of cost-benefit analysis:

> The EESC feels that cost/benefit analysis alone is not really an ideal tool for all areas and all consequences of legislation (e.g. public health, the environment). Indeed, the implementation of fundamental rights or general interest considerations which by definition are difficult to assess in terms of cost-benefit, is to be included in the analysis for certain projects.[54]

It also voices a comprehensive view on how IA should be used in the legislative process. The three pillars should receive equal weight and IAs should be accorded 'core importance' and 'no longer serve as necessary administrative exercises, or having no added value'. However, in spite of the importance of IA 'the results of impact analyses are not in themselves sufficient to justify instigating a proposal for legislation'. It is always 'necessary to substantiate the choice of legislative instrument or potential alternative to legislation (co-regulation, contracts, self-regulation) as stipulated in the interinstitutional agreement of December 2003 on Better Lawmaking, and from the viewpoint of its contribution to legal or administrative simplification for end-users'.[55] It is also desirable – in the view of the EESC – that 'the drafting stage should leave certain options open' so that 'drafts of a certain importance' can be scrutinised by the EU's advisory bodies, who, in their opinions 'should focus on the preliminary impact study, the objectives set and the ways to achieve them'.[56]

The Committee speaks in very negative terms about the idea to establish external review of Commission impact assessments:

> Certain 'think tanks' recommend establishing a European agency to monitor quality or to determine the relevance of legislation. It would be disproportionate, and against the letter and spirit of the Treaties, to create a superior authority to supervise legislation with the power to make changes. This would undermine the Commission's power – and duty – of initiative. At all events, the Committee is not in favour of setting up this kind of "super-agency" to monitor the exercise of the Commission's power of initiative. The Committee would instead stress the *ex*

52 EESC (Retureau opinion) (2005).
53 *Ibid.*, para 1.2.6.
54 *Ibid.*, para 4.7.
55 *Ibid.*, para 8.1.
56 *Ibid.*, para 8.2.

ante consultation procedures, the quality of preliminary impact assessments and the *ex post* assessments and consultation procedures.[57]

The European Economic and Social Committee has also commented on the IA process – or rather the lack of it – in at least one specific case. In its opinion on the proposed new support system for cotton[58] – the EESC pointed out that the Commission proposal was not accompanied by an impact assessment and called for specific analyses to be carried out before any further decisions were to be taken on amending the existing mechanisms. The revision of the cotton support system was later invalidated by the Court of Justice (see V.4.1) with the Advocate General expressly noting that the Commission's reaction to the EESC opinion was to 'not accept the proposed amendments (…) [n]or did it carry out an impact study'.[59]

V.4 REVIEW INSTITUTIONS

V.4.1 The European Court of Justice

The Court of Justice has not embarked on formal review of impact assessments so far. This section argues that this state of play is not surprising, given the established case law on the marginal review of the reason-giving requirement of Article 253 and the wide margin granted to the Institutions when it comes to applying the proportionality principle. However, the potential space for greater judicial involvement is worth exploring, not only because of the occasional pleas in favour of such a role[60] and because of the track record in other jurisdictions, but also because there are concrete signs that the Court may take an interest in IA.

57 *Ibid.*, para 8.2.20.

58 Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers and amending Regulations (EEC) No 2019/93, (EC) No 1452/2001, (EC) No 1453/2001, (EC) No 1454/2001, (EC) No 1868/94, (EC) No 1251/1999, (EC) No 1254/1999, (EC) No 1673/2000, (EEC) No 2358/71 and (EC) No 2529/2001 (OJ 2003 L 270, p. 1), inserted by Article 1(20) of Council Regulation (EC) No 864/2004 of 29 April 2004, OJ 2004 L 161, p. 48.

59 Opinion A-G Sharpston, para. 22.

60 Vibert (2005).

RIA review in other jurisdictions

In the US, courts are actively involved in the review of impact assessments.[61] Also, the GATT/WTO Panel has struck down regulations for – among other reasons – lack of scientific justification, for instance the EU Beef Hormone regulations.[62] In the UK context the debate on whether RIA could be judicially enforceable has been going on for more than a decade. Whereas Froud and Ogus argue that RIA is not capable of imposing any formal constraints on what regulators may lawfully do, because they are based on 'internal administrative directives',[63] Daintith and Page think that possibility cannot be excluded as we live in a 'world of legitimate expectations'.[64] To date there has not been any (high-profile) British court case directly involving the review of a regulatory impact assessment. The absence of a duty to give reasons for a legislative act makes this challenge more difficult to pursue for appellants. However, more informally, it seems that RIA can play a role in sustaining the substantive arguments of parties. Although inadequate reasoning behind an act is not a sufficient reason for setting it aside, the High Court has accepted that if the underlying reasons fall short (a state of affairs that could be brought to light by a RIA) this can add substance to the argument that the provisions under scrutiny are so flawed as to be irrational and unfair.[65]

In the shadow of judicial review

As Stone Sweet has put it '[t]he spectre of constitutional censure hovers over the legislative process',[66] meaning that much of the behaviour of legislative actors is influenced by the threat of judicial review – or the lack of it. The use of IA inevitably takes place in the shadow of judicial review. Alemanno sees a link between the threat of judicial review and the establishment and development of the IAB (see previous section).[67] It has also been suggested that the link between IA and judicial review is twofold.[68] On the one hand, judicial review can function as an incentive to prepare well-founded IAs to minimise the risk of legislation being quashed in court. On the other hand, the anticipa-

61 The RIA regime in the US has developed in such a way as to enable parties to use RIA as evidence before a court when challenging the legality of certain legal rules in judicial review proceedings. A famous case is *Donovan* v. *Castle & Cooke Foods Inc.* 692 F 641 (1982).

62 GATT/WTO Panel Decision in the Beef Hormone Case, n. 41 above. The Panel stroke down EU Beef Hormone regulations for lack of scientific justification among other reasons.

63 J. Froud and A.I. Ogus, 'Rational' Social Regulation and Compliance Cost Assessment' (1996) 74 *Public Administration,* 226.

64 Daintith and Page (1999), p. 277.

65 R. *v. Secretary of State for Environment, Food and Rural Affairs ex p. Leonard Kelsall* [2003] EWHC 459 (Admin), 35.

66 Craig and De Búrca (2003), p. 119.

67 Alemanno (2007), p. 15.

68 EVIA Hypotheses Paper (unpublished paper).

tion of judicial review by civil servants in charge of the development of the proposal could be a functional equivalent to IA: even if no official IA system is in place, tests that are substantively similar to those normally part of IA could be carried out in order to satisfy the information requirements of the court. Neither mechanism seems currently at work in the EU.

The role of evidence in legality review by the ECJ

In reviewing concrete decisions in the area of competition law, the Court of Justice is known to look at whether the evidence relied on in the decision-making process is accurate and complete, therein allegedly stretching its competence as defined in Article 230 TEC by not limiting itself to review of the legality of EC acts.[69] To what extent can this reasoning be extended to review of legislative acts and does that mean that the Court will look at impact assessments in its review process? Two questions are central here:

1. who carries the 'burden of proof' in the case of regulatory proposals?
2. what is the standard of proof and who determines it?

Case law predating the adoption of the IA regime in 2002, most notably the Pfizer case,[70] has stipulated that whereas some economic or scientific assessment is required, the Institutions still have a rather large degree of discretion in carrying out these assessments. The following paragraphs look along three 'tracks' for potential space for IAs in the judicial activity of the Court of Justice:

- Duty to give reasons;
- Subsidiarity principle;
- Proportionality principle.

Duty to give reasons

The duty to give reasons for the EU legislator, or in legal terms the reason-giving requirement of Article 253 looks the most promising as a candidate vehicle,[71] but is in fact only marginally reviewed for by the ECJ. Even for decisions of an individual nature the Court has been careful not to construe the duty to provide reasons in such a way as to include participatory rights for stakeholders[72] stating that the Commission is not required to discuss all

69 S. Lavrijssen and M. De Visser, 'Independent administrative authorities and the standard of judicial review' (2006) 2 *Utrecht Law Review*, 111-135.

70 *Pfizer Animal Health v Council*, Case No. T-13/99 [2002] ECR II-3305.

71 The text of Article 253 TEC reads: "Regulations, directives and decisions adopted jointly by the European Parliament and the Council, and such acts adopted by the Council or the Commission, shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained pursuant to this Treaty."

72 Craig and De Búrca (2003), p. 373.

the issues of fact and law raised by every party during the proceedings.[73] Given the assertion in the case law that the statement of reasons is required to contain only less elements when a measure is of a general legislative nature, it is unlikely that the Court will interpret Article 253 in such a way as to oblige the Commission to enter into a dialogue with stakeholders any time soon. The same applies to consideration of the full costs and benefits of proposals or any preparatory activity similar to what currently is the IA procedure. Indeed, as long as the statement of reasons clearly discloses the essential objective pursued by the Institution, the Court does not require a specific statement of reasons for the various technical choices made.[74]

Subsidiarity

There is case law which ties the duty to motivate[75] to compliance with the subsidiarity requirement but this – as is common for subsidiarity review – remains limited to marginal review and certainly does not mention impact assessment. So far the Court of Justice has not gone along with arguments put forward by parties that whenever it is possible to make a quantitative assessment of a market in order to determine whether the subsidiarity principle is complied with, such an assessment should be obligatory. Of course this might change if there is an obligation for the Commission to make these assessments in IA (even if it is self-imposed) and b) there are IA reports, laying bare the Commission's reasoning, that can be brought into the courtroom for the Court to look at, but for the moment there are no concrete signs pointing to such a development.

Proportionality

Tangible clues pointing to a legal link between the proportionality principle and impact assessment abound however. The various stages of proportionality (suitability, necessity and proportionality *stricto sensu*) implies some kind of 'impact assessment'. The question remains though '*what kind of* impact assessment?' and in the context of this thesis specifically: are there cases in which the Court requires a fully fledged impact assessment, now that the IA system is in place? As Craig and De Búrca note, in the type of cases in which an individual argues that the very policy choice made by the administration is

73 *Stichting Sigarettenindustrie v. Commission*, Cases No. 240-242, 261-262, 268-269/82 [1985] ECR 3831, para 88.

74 *Spain v. Council*, Case No. C-284/94 [1998] ECR I 7309, para 30.

75 The ECJ decided that Article 190 (now 253) did not require an explicit reference to the subsidiarity principle as long as the reasons why EC action was necessary were stated in the recitals. *Germany v. European Parliament and Council*, Case No. C-233/94 [1997] ECR I-2405.

disproportionate,[76] the Court is likely to review for proportionality not too intensively and will quash the regulation or the policy only when it is clearly or manifestly disproportionate.

Case law mentioning IA

Up to date there have been two instances of IA playing an explicit role in procedures before the Court of Justice.

The IATA case

The first is in the judicial review proceedings the International Air Transport Association (IATA) and the European Low Fares Airline Association (ELFAA) had brought before the High Court. In a preliminary reference the Court of Justice[77] was asked to rule upon the validity of the controversial Regulation 261/2004 on Air Passengers Rights.[78] Alemanno reports that the parties in this case have put forward the argument that the Commission has violated the IA Guidelines and have argued that the IA as performed by the Commission on the original legislative proposal was incomplete because it did not explore all the policy options available. He continued:

> Although the Court has not replied to this argument, it is not excluded that it had glanced at it when considering the proportionality of the indemnities as provided for by the Regulation.[79]

However it should be noted that the two Commission legislative proposals relating to the regulation dated from 2001 and 2002 respectively,[80] thus predating the adoption of the IA procedure proper,[81] which would have made it difficult for the Court to explore this argument further, had it wanted to do so.

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76 The other types of proportionality review cases are those where the individual argues their rights have been unduly restricted by EC administrative action and those where it is argued the penalty imposed is disproportionate. Craig and De Búrca (2003), p. 373.

77 *IATA and ELFAA*, Case No. C-344/04 [2006] ECR I-403.

78 Regulation (EC) No 261/2004 of the European Parliament and of the Council of 11 February 2004 establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights, and repealing Regulation (EEC) No 295/91.

79 Alemanno (2007), p. 12.

80 COM(2001) 784, modified proposal COM(2002) 717.

81 COM(2002) 276 final.

Spain v Council

In the second case, the appearance of IA is more substantial. To some observers case C-310/04 *Spain v. Council*[82] is 'pretty much a textbook case on annulment actions and on how the Court approaches judicial review".[83] In the eyes of others it 'demonstrates and confirms the Court of Justice's increasing interest in this issue'.[84] The main issue in this case that has inspired such diverging reactions was that Commission and Council had amended the rules on the aid to cotton farmers, decoupling, aid from actual production because the old system only led to overproduction. Spain objected and took the case to court, its main argument being that Commission and Council had failed to take labour costs into account, leading to a disproportionate outcome in the regulation concerned. On 16 March 2006 Advocate General Sharpston in her opinion on this case explicitly mentioned impact assessment, a first in the history of the ECJ. More precisely, the lack of impact assessment was treated as a self-standing and decisive factor in concluding that proportionality had been breached:

> In the absence of any impact study, certain choices made by the Commission and the Council appear arbitrary.

The Advocate General reminds us that the standards of the proportionality tests are less strict for the Institutions than for Member States when they are justifying national measures under Article 30 TEC. But although 'judicial review must be limited to examining whether the measures are 'manifestly inappropriate' to the aims pursued', the restrictions do not go as far as to exempt the Institutions 'from carrying out any examination of the adequacy of the contested measures to the set objectives'. And thus:

> The Community institutions must, in any event, be in a position to justify their legislative choices if these are challenged before the Court under the proportionality principle.[85]

82 *Spain v. Council*, Case No. C-310/04 [2006] ECR I-7285.

83 EU Law Blog, 'Reform of the common agricultural policy and annulment: Case C-310/04', post of 10 September 2006. See http://eulaw.typepad.com/eulawblog/agriculture/index.html (last accessed 1 December 2006).

84 MEP Lehne made this remark during the plenary debate on Better Regulation on 4 April 2006, referring to the conclusion of the A-G specifically.

85 Opinion of Advocate General Sharpston of 16 March 2006, C-310/04 *Spain v Council*, paras. 80-81.

The Advocate General seems prepared to tie the lack of information on the part of Commission and Council directly to the absence of an impact assessment:

> The failure to carry out an impact study leads to a number of obvious questions.[86]

The Commission had submitted that no IA was required in this case:

> [B]ecause the support system for cotton is simple when compared with other common market organizations (i.e., a simple mechanism links internal support price and external world market price), *an impact study was unnecessary*.[87]

Whereas the A-G could not go along with the Commission's defence, she showed some sympathy for the Council's argument 'that it was under no obligation to consider the impact of the reforms upon ginning enterprises', but could only agree with it *in general terms*, since 'in the present case, there are particular features'.[88]

The Court agreed on the outcome of her conclusion and annulled part of Council Regulation 864/2004 for breach of the principle of proportionality. It also concurred with the Advocate General in that failure by the Council and Commission to take into account certain relevant costs, were of crucial importance. However, it did not attach similar importance to the absence of an official IA as such. The Court confirmed that it can only exercise limited judicial review in this case because of the broad discretion the Institutions enjoy:

> It is true that where, as in the present case, the Community legislature has to assess the future effects of legislation to be enacted although those effects cannot be accurately foreseen, its assessment is open to criticism only if it appears manifestly incorrect in the light of the information available to it at the time of the adoption of the legislation in question. (…)It is also true that the Community legislature's broad discretion, which implies limited judicial review of its exercise, applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts.[89]

However, the following wording is of interest for future cases about the accuracy of impact assessments:

> [E]ven though such judicial review is of limited scope, it requires that the Community institutions which have adopted the act in question must be able to show before

86 *Ibid.*, para. 89.
87 *Ibid.*, para. 83. Emphasis AM.
88 *Ibid.*, para. 85.
89 Case C-310/04, paras. 120-121.

> the Court that in adopting the act *they actually exercised their discretion*, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate.[90]

This leads to the formulation of a minimum standard for the evidence-base of legislation produced by the EU legislator:

> [T]he institutions must at the very least be able to produce and set out clearly and unequivocally the basic facts which had to be taken into account as the basis of the contested measures of the act and on which the exercise of their discretion depended.[91]

Furthermore, the Court remarked that

> [t]he circumstance relied on by the Commission that obtaining that information would have raised certain technical problems cannot call into question its relevance.[92]

This specification could be of relevance for future cases involving impact assessment and could stand in the way of a pragmatic interpretation of the principle of proportionate analysis (see III.2.1) in particular.

The reception of the case law in the European Parliament

A circumstance that could speed up the institutionalisation of IA even further is the way in which case C-310/04 has been received in the European Parliament. The case, and in particular the opinion of the Advocate General in that case, has caused quite a stir in the European Parliament. Civil servants within the Parliament see this annulment as a sign that Better Regulation is becoming increasingly serious: the evidence-base of lawmaking is getting more important and IA is the way to achieve it.[93] The case was also mentioned at a training seminar on impact assessment in the European Parliament, where a senior lawyer from the Parliament warned the audience, mostly consisting of officials working in the Parliament that the choice to do an IA is up to the legislator, but that this case shows that in the future the European Parliament too may be obliged.[94]

Anecdotal evidence that the idea of the Court of Justice reviewing impact assessments is no longer alien to MEPs is provided by the minutes of a meeting

90 Case C-310/04, para. 122.
91 Case C-310/04, para. 123.
92 Case C-310/04, para. 126.
93 Informal communication European Parliament official. Similar wording was also used in an internal press release.
94 European Parliament, Training seminar on impact assessment, 8-9 February 2007.

of the AllChemE seminar series which stated that '[t]he question of a legal challenge to the REACH impact assessment was raised' apparently at the instigation of MEP Caroline Jackson who 'asked if industry had considered challenging the impact assessment in court'.[95]

What trend in judicial review of IA?

Although the ECJ plays a role as constitutional enforcement mechanism, the information requirements it has set for the Institutions are rather limited, as this section has made clear. The analysis above shows that it is premature to declare a general link of a legal nature between the impact assessment procedure and proportionality review by the Court of Justice. The 'standard of economic proof' formulated by the Court in case C-310/04 is very much connected to the specificities of the Common Agricultural Policy (CAP). True, an impact assessment could have satisfied the Court's information requirements, but it could also very well not have done so, as it is plausible that the Commission would have left out labour costs from a proper IA as well. It is also clear that a comparative study of a much simpler nature than an IA could have sufficed, had it taken into account labour costs and the effect on ginning plants.

However if the extensive wording on the absence of an IA by the Advocate General has any predictive value, the standards for IA used by the Institutions, in particular their adequacy for informing the Court, could well become a judicial subject in the next few years. *Spain v Council* could pave the way for tying information requirements to IA. It is not the specific case which is in itself important, but rather the fact that IA was treated as a meaningful parameter shaping the policy powers of the legislative bodies in general.[96] The reception of the case in the European Parliament could have a self-fulfilling function here in making IA part of the hierarchy of norms enforced by the Court in its constitutional role.

Because the standards for information requirements set by the Court are decidedly low, it is unlikely that a parallel system of gathering economic evidence based on the Court's standards rather than on the Commission's internal standards will develop in the EU. However, if the Court will move into the realm of IA a bit more by demanding an increasingly factual justification of a Commission proposal away from a narrow focus on finding a legal

95 The AllChemE Seminars, 'Where science meets society. The socio-economic importance of chemistry in Europe', 3 Available at http://www.allchemeseminars.org/downloads/04-01-28/Final%20Report%20%2028-01-04.pdf (last accessed 15 July 2007).

96 C.f. De Búrca, who points out the landmark Tobacco case was also not meaningful as an instance of litigation in and of itself.

basis in the Treaties,[97] it will be interesting to see whether the standards it develops will match those of the IA procedure.

V.4.2 European Court of Auditors

Following the example of the NAO?

It has been suggested in the literature that the European Court of Auditors could play a role in assessing the quality of Commission IAs, possibly along the lines of the annual review by the National Audit Office (NAO) of British RIAs.[98] The NAO took on its new role after a recommendation the Public Accounts Committee in its report on making good use of regulatory impact assessments of April 2002 prompted the Better Regulation Task Force (BRTF) to invite the NAO start evaluating RIAs independently.[99] The NAO has so far published four reports, the first two of which evaluated a sample of RIAs from across Government, whereas the third contained a broader assessment which included procedural issues of four government departments.[100] These reports tend to be fairly critical and the fourth edition was no exception, identifying the use of IAs in the decision-making process as the main weakness with fewer cases of poor quality analysis.[101]

Despite some criticism that the RIAs chosen by the NAO as samples are random and too small in number, this new review procedure is already well established and the NAO reports on RIA are always eagerly anticipated by practitioners, stakeholders and academics. The main advantage of this procedure – it provides for independent review carried out by a well-respected body rather than one that has to be newly established – is also mentioned by Mather and Vibert when they propose to involve the Court of Auditors in EU IA. Another advantage they mention is that '[i]t would move with the tide of modern governance in broadening traditional conceptions of "audit"'.[102]

However, this initiative cannot be transposed one-on-one to the European level. Mather and Vibert themselves mention the lack of experience and apparent reluctance – to move into IA specifically and to interpret 'audit' in a broader way generally – on the part of the Court of Auditors, as well as its distance from the Commission. As a last disadvantage the authors assert that

97 European Policy Forum (2004).
98 Mather and Vibert (2006), p. 31.
99 National Audit Office Press Notice, Regulatory Impact Assessments – the NAO's new role, 2 December 2002. Available at http://www.nao.org.uk/pn/02-03/0203ria.htm (last accessed 15 July 2007).
100 National Audit Office (2004); National Audit Office (2005); National Audit Office (2006); National Audit Office (2007).
101 National Audit Office (2007).
102 Mather and Vibert (2006), p. 31.

it is not clear 'how it could trigger sanctions with any bite under its existing powers'.[103] Indeed, the limits imposed by existing powers are a problem here. After all, the principle of conferred powers governs the competence allocation to European Institutions rather strictly (Article 7 TEC). Article 248 TEC states that the Court of Auditors shall examine the accounts of all revenue and expenditure of (bodies set up by) the Community, examine whether all revenue has been received and all expenditure incurred in a lawful and regular manner and whether the financial management has been sound. But the auditors also have a 'left-over competence', laid down in Article 248(4), second subparagraph, TEC, that could offer a way out should they want to occupy themselves with IA practice by the Commission:

> The Court of Auditors may also, at any time, submit observations, particularly in the form of special reports, on specific questions and deliver opinions at the request of one of the other institutions of the Community.

A review of the practice so far renders it unlikely however that – without any endorsement or request from the Commission – the Court of Auditors would use this competence to issue 'special reports' to review Commission IAs in a NAO-like fashion.

Examples from an emerging practice?

There has been no report especially on the topic of IA by the Court of Auditors to date. However, IAs occasionally features in regular reports and opinions by the Court of Auditors. In one of its opinions, on a proposed revision of the Regulations applicable to the management of the Structural and Cohesion Funds,[104] requested by the Council, the Court of Auditors explicitly took the extended impact assessment[105] into consideration.

> The extended impact assessment fails to address the reasons for maintaining separate Funds (as opposed to grouping the Funds as postulated in Article 161 of the EC Treaty). However, this should have been the subject of a thorough analysis from the point of view of the advantages and disadvantages of all the available options, given that the extended impact assessment gives arguments in favour of setting up a single Fund. As regards the present Objective 2, in fact, it says that the relative thematic diversity of funded projects and the fragmentation caused

103 D. Wilkinson, C. Monkhouse, M. Herodes and A. Farmer, *For Better or for Worse? The EU's 'Better Regulation' Agenda and the Environment* (London, 2005), p. 11.

104 Opinion No 2/2005 on the proposal for a Council Regulation laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund (COM(2004) 492 final of 14 July 2004) (2005/C 121/02) adopted by the Court of Auditors in Luxembourg on 18 March 2005.

105 SEC(2004) 924.

> by zoning have blocked the implementation of suitable policies. Moreover, it has not been possible to exploit sufficiently the ERDF/ESF synergies under Objective 3. It is therefore concluded that there is a need for:
> · a greater concentration of themes to promote competitiveness,
> · greater complementarity, over and above the 'Convergence' objective, between the ERDF and the ESF.[106]

More frequent are the references to IA by the Commission in its replies to the Court's findings. For example when arguing that the preparation of the 1998 reform of the tobacco sector had in fact been thorough the Commission put forward the following:

> In 2001 the Commission introduced a broader and more systematic interdepartmental consultation. In addition, since 2003 an extended impact assessment is carried out for all major proposals made and presented to the other institutions along with the legislative proposal. The tobacco reform adopted by the Council in April 2004 was subject to this new procedure and 16 departments took part in the impact assessment, including DG DEV, DG ENV, DG COMP and DG TAXUD.[107]

In relation to comments from the Court in its annual report of 2003 on the management and supervision by the Commission of control measures and expenditure relating to foot and mouth disease, one of the remarks by the Commission was:

> In agreement with the request of the European Parliament, the Commission launched a study on existing compensation schemes in Member States and received the final report in October 2003. As a matter of follow-up and based on dedicated budget arrangements, a further study should provide exact expert estimates and calculations to carry out an impact assessment. These will be discussed with the Chief Veterinary Officers in September 2004 and will be presented to the International Conference on the prevention and control of infectious animal diseases in December 2004.[108]

In the same annual report in the context of 'sound financial management audit of the common organization of the market in raw tobacco' the Court said that the Commission's monitoring was unsatisfactory and the evaluation of the CMO was delayed. The Commission replied that it was of the opinion that its

106 C 121/18, para. 24.
107 C 41/1, 17 February 2005, para. 34 of the Commission's reply. The abbreviations stand for DG Development, DG Environment, DG Competition and DG Taxation and Customs Union.
108 Court of Auditors – Annual report concerning the financial year 2003, OJ C 291, 30 November 2004, para. 4, 112, C 293/134.

monitoring proved satisfactory, stating the completion of an extended impact assessment as one of the reasons.[109]

An example of how recommendations by the Court of Auditors can steer if not part of the content then at least the focus of a Commission IA can be found in a report in which the Court of Auditors audited the effectiveness of this aid scheme based primarily on a random sample of 30 operational programmes in eight Member States and on a review of Commission data.[110] Throughout its reply the Commission makes various references to 'the on-going impact assessment' that will address the issue of effectiveness, as well as the coherence between the CMO Fruit and Vegetables and rural development (RD) programming. One of the Court's core recommendations is that the Commission considers the merits of alternative approaches to simplify and reduce the costs of the scheme and improve the effectiveness of the aid. The Commission 'agrees with the aims expressed in the Court's recommendations and will, as part of the impact assessment, explore how best they can be achieved'.[111]

Whether this last example is just a one-off or will develop into a practice of providing substantive input for IAs on a more regular basis remains to be seen. In any case a slow development in this direction seems more likely than the sudden adoption of the 'NAO model'. As is the case with any potential structural involvement of co-actors in the early stages of the IA process, the limits of unconstitutional interference with the Commission's right of initiative lie remain underexplored.

V.5 Regulatory bodies

V.5.1 Committees

Comitology is the needlessly confusing term commonly used for the procedure by which the Commission exercises its implementing powers – granted by a regulation or directive – under the supervision of a body of national civil servants who have the power to block the proposed implementing measure and refer it to Council. The familiar argument against comitology – at least in the system predating the 2006 reform – is that it limits the input of the European Parliament. However, these days – in line with the heated atmo-

109 C 293/144, para. 4, 136. Another example is: Special Report No 9/2004 on Forestry Measures within Rural Development Policy, together with the Commission's replies (2005/C 67/01), para. 73 C 67/26: " The conclusions of the Salzburg conference have been used as an input for the extended impact assessment on rural development which accompanied the Commission's proposal for a new regulation for the next programming period".

110 Court of Auditors, Special Report No 8/2006 'Growing success? The effectiveness of the European Union support for fruit and vegetable producers' operational programmes'.

111 Special Report No 8/2006 'Growing success? The effectiveness of the European Union support for fruit and vegetable producers' operational programmes', p. 55.

sphere around Better Regulation initiatives – a new argument can be heard: comitology 'bypasses the Commission's impact assessment procedure, thus effectively excluding broad stakeholder involvement as well'.[112] In view of the widely acknowledged legitimacy problems surrounding comitology as a mechanism for regulatory decision-making, it is not surprising that the question whether IA should be used in comitology procedures is often raised.

Reforming comitology

In June 2006 the three Institutions successfully concluded negotiations on a reform of the comitology procedure and on 17 July 2006 the Council took the formal decision to amend the 1999 Decision on comitology introducing a new procedure, known as the 'regulatory procedure with scrutiny'.[113] This procedure is a watered down version of the proposed 'call back right' of Article I-35 of the draft Constitutional Treaty and kept campaigning for after the crisis of the referendums. Since the reforms Parliament is able to veto measures taken by the Commission through comitology but will not have the power – foreseen in the draft Constitutional Treaty – to revoke the Commission's implementing power in specific cases. MEP Doorn has – before the reform came through – suggested that in order to allow the European Parliament to focus more on the broad lines of legislation it should not only be given a call back right for comitology rules but also an obligation to conduct impact assessments on comitology decisions should be introduced.[114] In his own words in the draft report:

> [M]uch secondary legislation comes into being via the 'comitology procedure'; considers that *such legislation must meet the same quality requirements as primary legislation and that it must therefore also be subject to impact assessment*; considers, further, that Parliament should have the right, in the context of quality assurance for European legislation, to subject comitology legislation to Parliamentary approval *should an impact assessment indicate that this is necessary*; calls on the Council and Commission to enshrine this procedure in an inter-institutional agreement in the near future.[115]

A remarkable aspect of this statement is that it is proposed to use IA to select committee decisions that should be subject to parliamentary approval. Because

112 Wilkinson and Monkhouse et al., p. xiii.

113 Council decision of 17 July 2006 amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission (2006/512/EC), OJ L 200/11.

114 See e.g. the remarks of MEP Bert Doorn at a hearing at the British House of Lords, Select Committee on European Union, Minutes of Evidence, Examination of Witnesses (Questions 20-39), 13 June 2005. Http://www.publications.parliament.uk/pa/ld200506/ldselect/ldeucom/25/5061303.htm (last accessed 15 July 2007).

115 EP Doorn report (2006), para. 6, p. 5. Emphasis AM.

the 'original EU IA', impact assessment by the Commission is certainly not used to highlight the necessity of involvement of a particular body or institution, this proposal is certainly innovative. However, it remains unclear which criterion would be used to determine whether parliamentary involvement is necessary. Would it involve some sort of cost threshold? Would an IA be compulsory when a committee wants to choose an option that does not bring about the greatest net benefit? Or should we think more along the lines of an indication that particular societal groups or human rights are at stake? The Doorn report put a lot of faith in IA:

> Another important thing is to ensure that legislation adopted under the comitology procedure is submitted to an impact assessment. This both guarantees the quality of legislation and creates greater transparency in this process, which is not subject to parliamentary control.[116]

The final version of his report added an important qualification: legislation decided in comitology 'must meet the same quality requirements as implemented legislation and will therefore be subject to impact assessment, *once the necessary know-how and tools have been developed*'.[117] A kind of package deal was even offered:

> [I]f the Parliament's legislative powers are respected in the context of comitology, it will be more willing to focus on general principles and support legislative simplification and innovation.[118]

So although the Parliament admitted that implementation would be difficult, the idea is that impact assessment would come to serve as a tool for Parliament to monitor the exercise of comitology powers by being informed about the costs and benefits as well as the general impact of comitology decisions, without having to go into the technical details themselves. MEP Lehne concurred:

> I think it is crucial that decisions arrived at by way of comitology also need to have their impact assessed. There are a whole load of cases that we could take as examples, where the real bureaucratic madness lay in the comitological decisions rather than in the legislation itself, so, here too, there needs to be proper monitoring of what impact laws have.[119]

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116 *Ibid.*, explanatory statement, p. 7.
117 *Ibid.*, p. 11.
118 EP Frassoni report (2006), para. 6.
119 MEP Lehne during 4 April 2006 plenary debate on Better Regulation. Http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20060404+ITEM-013+DOC+XML+V0//EN&language=EN (last accessed 15 July 2007).

This proposal is reminiscent of the US system where regulatory impact assessment is used to control the exercise of delegated legislative powers by agencies, only there it is the White House (through the OMB) that scrutinises the impact assessment, not Congress as a perfect analogy would have implied.

The Commission Communication on Compliance with the Charter of Fundamental Rights in Commission legislative proposals[120] draws attention to the problem that regulatory decisions taken by the Commission by virtue of its implementing powers can also be sensitive as regards fundamental rights. The solution offered in the same communication is that when the lead department considers it justified by the scale of the foreseeable impact of a regulation and the legal framework allows it, an assessment may be conducted by way of exception.[121]

At conferences on EU IA – of which quite a few have been organized in the past years – it is also a popular theme for questions: why is there no obligation for committees to carry out an IA when their perceived legitimacy gap could so well be addressed by IA? Not only could IA force committees to be more accountable (to Parliament, to stakeholders and to the general public), but a requirement to put down the motivations for their regulations as well as their impacts on paper could also make the decision-making in comitology more transparent. It is important to see that introducing a requirement for committees to conduct IA will not incur a net increase in their accountability and transparency; the use of IA in comitology would come with its own trade-offs. The question need to be asked: what kind of IA procedure would bring what kind of changes in the way these Committees make their decisions?

It is important to acknowledge the fact that the introduction of IA could undermine the committees' reason for existence, their perceived efficiency. Comitology has been called into existence in order to allow technically correct implementing measures as required by EC secondary legislation to be taken in such a way that they are workable in the Member States and can be easily updated. This is not to say that certain other legitimizing values should not be enhanced, but the least desirable outcome is the creation of a paralysed decision-making body.

The discussion on IA and comitology in many respects mirrors the debate between those who see committee governance as a potential forum for deliberative democracy[122] and those who think that perspective is detrimental to democratic accountability in the EU. Someone who favours the deliberative approach is looking at an IA model that can enhance the quality of the internal debate (see II.3.5) whereas an opponent will probably reason from a more

120 COM(2005) 172.
121 *Ibid.*, 4.
122 Joerges and Neyer (1997).

traditional democracy perspective and search for a type of IA that can fit in with those (see II.3.4 or II.3.2).

Furthermore, the Commission IA procedure cannot be translated one on one to the comitology setting. It is difficult to see how consultation could be an integral part of a comitology IA procedure when the participatory qualities are explicitly limited to national experts. Because of that, the use of IA could face some of the same problems as the use of IA in the Council of Ministers does. Even if it is obvious that the Commission would prepare the IA, the role of the Member States in this would be unclear. Also, the type of regulations prepared tends to be different. Although no one will deny that comitology regulations can have far-reaching impacts on businesses and citizens, they are often required by the authorizing primary instrument, raising questions about the added value of an impact assessment at this late stage. Not only does this mean that no meaningful assessment of the 'no action' option can take place, it also implies that the rough estimates used for widely varying policy options that are used in 'regular' Commission IAs are unsuitable. Assessing the impacts of the much more technical regulatory options open to committees could well take more sophisticated methodologies, more money, more time or a combination of those. This is not to suggest that the regulatory decisions made in comitology do not involve real choices; they do and often even of a political nature. It is a matter of thinking through what introducing IA to comitology would mean in practice instead of riding along on the Better Regulation waves and putting the burden of solving legitimacy problems on the shoulders of IA once again.

As explained in section III.3 the scope of the Commission IA procedure is not a matter for the guidelines, but the selection of initiatives to be subject to IAs is a political decision and it is currently connected to the Commission Legislative and Work Programme (CLWP). The most recent development in this regard is that the Secretary-General of the European Commission has announced in a speech that as of 2008 the range of initiatives for which an IA is required will be extended to also more systematically cover items with significant potential impacts which are not included in the CLWP, including selected comitology items.[123] In particular, the 'prompt letters' that the Impact Assessment Board (IAB) can issue, may be directed at comitology measures (see III.4.2). The Commission has also made it clear al along that DGs are free to perform extra IAs if they deem it necessary. For instance, the internal guidelines issued by DG Health and Consumer Policy (SANCO) for the preparation of 'SANCO Scoping Papers' – a document related to impact assessment – recognise that Scoping Papers may be required for major implementing measures taken in comitology.

123 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).

'Lamfalussy' committees

Lamfalussy comitology is special because of the extra layer of committees consisting of national regulators which have been inserted into the procedure.[124] Complex inter-institutional difficulties have arisen from the establishment of the Lamfalussy system for securities market regulation. It can be problematic that implementing measures at level three fall outside the historical institutional structure. The European Parliament has displayed considerable resistance against the use of Lamfalussy procedures, fearing a watering down of its own legislative powers and lower levels of transparency.[125] These problems have not yet been solved but already the new Lamfalussy-style committees on banking supervision and insurance have been put in place.[126]

Concrete steps have been taken to bring the Lamfalussy system – called a 'test case' for a 'dynamic legislative process'[127] by the European Parliament – up to speed with the Better Regulation programme. The ECOFIN Council has held a meeting with the Chairmen of the three 'level three' Lamfalussy Committees[128] to discuss progress and opportunities for Better Regulation in the supervisory field. The three Committees (CEBS, CESR and CEIOPS) are already planning to make greater use of the following tools: economic analysis (including risk assessment and cost benefit techniques), consultation and transparency, risk based implementation and post implementation reviews.[129] Finally, a report by Commission services on the performance of the Lamfalussy system states that 'all major Level 1 measures will in future be subject to a regulatory impact assessment';[130] this will not be easy, because the consultation by the committees has rather tight timetables.[131]

124 Lamfalussy Committee of Wise Men, *Final Report of the Committee of Wise Men on the Regulation of European Securities Markets (Lamfalussy report)* (Brussels, 2001).

125 N. Moloney, 'The Lamfalussy Legislative Model: A New Era For The EC Securities and Investment Services Regime' (2003) 52 *International and Comparative Law Quarterly*, 515.

126 Directive 2005/1/EC of the European Parliament and of the Council of 9 March 2005 amending Council Directives 73/239/EEC, 85/611/EEC, 91/675/EEC, 92/49/EEC and 93/6/EEC and Directives 94/19/EC, 98/78/EC, 2000/12/EC, 2001/34/EC, 2002/83/EC and 2002/87/EC in order to establish a new organizational structure for financial services committees, OJ L 79, 24 March 2005, pp. 9–17.

127 EP Frassoni report (2006).

128 Arthur Docters van Leeuwen (CESR – Committee of European Securities Regulators), Jose-Mariá Roldán (CEBS – Committee of European Banking Supervisors) and Henrik Bjerre-Nielsen (CEIOPS – Committee of European Insurance and Occupational Pensions Supervisors).

129 'Progress and opportunities for better regulation', Introduction by Henrik Bjerre Nielsen, Meeting between Lamfalussy Chairs and ECOFIN, 11 October 2005. Available at http://www.c-ebs.org/speeches/SP17.pdf (last accessed 28 May 2007).

130 SEC(2004) 1459, p. 11.

131 See also Mather and Vibert (2006).

V.5.2 European agencies

Although the suggestion that EU agencies should engage in IA by analogy of their American counterparts is one easily made, it is very hard to imagine what the agencies would be doing IA on, since they virtually lack regulatory powers in the 'standard-setting' sense.[132] That explains why the debate on using IA to control exercise of delegated regulatory powers in the EU context has concentrated on committees, perhaps the nearest equivalent to the American agencies at the EU level. Yet there is another type of possible involvement to be explored. Mather and Vibert have proposed that Parliament could make use of EU agencies in gathering EU-wide data and performance indicators for parliamentary IAs.[133] The authors suggested that 'EU agencies would have an incentive to cooperate in this area because it would be a role consistent with their information gathering role and not one that would lead to friction with other bodies such as the Commission'. Some agencies, such as the European Food Safety Authority (EFSA) already issue opinions for the benefit of various public authorities. There is one example of a request for assistance in the context of the general impact assessment framework. MEP Caroline Jackson, the Environmental Committee Chairman 1999-2004 has creatively appealed to the European Environmental Agency (EEA) for help:

> Given the EEA's independence from vested interests, the European Parliament will be looking for the EEA to play a key role in providing assessments of the environmental impacts, both of proposals as a whole and of important specific aspects of and amendments to such proposals, and to respond to requests in this sense from the European Parliament.[134]

The response from EEA director Jacqueline McGlade of 16 February 2004 can be interpreted as a limited promise to help:

> Thirdly, we aim to develop our capacities for providing more ad hoc support for rapporteurs and other interested Members; addressing issues that have not been covered in the preparation of the proposal. Requests for impact assessments also fall into this category. All staff are now allocating some of their time to cover such contingencies. However, it is important to underline that the Agency will not be able to react within time limits suitable for the legislative process if the data and information needed for a proper impact assessment is not readily available. In such cases we might therefore have to limit ourselves to outlining the information that would be needed to answer the request.[135]

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132 For a list of all Community agencies see http://europa.eu/agencies/community_agencies/index_en.htm (last accessed 18 July 2007).

133 EP Activity report ENVI Committee (2004), p. 72.

134 Extract from letter from Caroline Jackson (Environmental Committee Chairman 1999-2004) to the executive director of the European Environment Agency on their future relations.

135 *Ibid*.

V.6 PRIVATE CO-ACTORS

V.6.1 Citizens

The idea 'that it is important to assess the impact of proposed measures and review existing regulation from the point of view of those affected',[136] is at the core of the Better Regulation policy. From a legitimization perspective, the contribution IA could make to easing the general credibility crisis (see II.1.3) by strengthening the communication between the EC Institutions and the citizens is interesting for legislators to explore. As an MEP put it:

> If we are to gain the confidence of our citizens, consumers and businesses and enhance the credibility of the EU as an effective and relevant legislator by taking up the challenges and opportunities in the global world, then we need to improve the way that we make European laws.[137]

At the Conference on Subsidiarity held by the Dutch Presidency on 17 November 2005, Dutch minister of European Affairs Atze Nicolai used the metaphor of a train for Europe, adding that citizens do not know 'how much it costs, where it is heading or even who is driving the train.'

IA as an information tool for citizens can take different forms. First of all, regulators can use IA to actively publish information on impacts of new regulatory initiatives. In the US this service is juridified through the Regulatory Right-to-Know Act which promotes the public right-to-know about the costs and benefits of Federal regulatory programs and rules. The rhetoric employed by Nicolai shows that the American approach is increasingly seen as an example, although the debate on the development of the impact assessment system has so far not seen anyone arguing directly in favour of such a legal 'right to know', in line with the prevailing scepticism regarding the objectivity of cost-benefit analysis. Certainly, the European Commission publishes all impact assessment on a website (see III.3.4), but this is presented very much as a service and not as a duty. Expectations on the part of the citizens as to what these IA reports contain are not encouraged and the Commission does not engage in any kind of aggregate reporting on regulatory costs and benefits. It is difficult to imagine that many citizens will visit the Secretariat-General's webpage which contains all the IA reports[138] regularly to be informed about the reasons behind Commission proposals. On the other hand, better information provision by the Institutions could feed into journalistic articles that are read by the wider public.

136 SEC(2005) 1329, p. 24.
137 McCarthy and Frassoni (2005) (contribution Arlene McCarthy MEP).
138 Http://ec.europa.eu/governance/impact/practice_en.htm (last accessed 15 July 2007).

The second form for the link between IA and the citizen to materialise is through input into the decision-making process, along the lines of the participatory and deliberative models of lawmaking (see II.2.5 and II.2.6). However, the consultations organized by the European Commission tend to be implicitly aimed at organized groups of stakeholders (see V.6.2). Although in theory there is no reason why a citizen could not submit a consultation reaction – at least not in the public consultation processes – this mode of action usually requires a considerable degree of organization and expertise, making direct involvement of citizens through this channel a hypothetical governance tool.

The third form in which citizens can be present in IA, embraces the hypothetical nature of the citizen's role in the IA process that was described above as problematic. The 'citizen' can still serve as a valuable reminder to those involved in policy development that citizens are in fact affected by regulatory interventions and that this is an important reason to think carefully about where the impacts will fall and how large they are likely to be. This can for instance require correcting for a special interest focus bound to be present in most consultation reactions.

V.6.2 Lobby groups

The characteristic that sets lobby groups[139] apart from the categories of co-actors discussed in previous sections is that they are not public bodies in any sense so they are in principle free to act as long as they do not trespass any legal limits set on the private sphere. The line between public and private actors in governance structures is difficult to draw. From a perspective of constitutional law the distinction matters a lot. Those within government can be vested with formal powers those without cannot. However, since no special competence is needed to engage in IA (see II.3.3) the step from having a special interest to having special standing is much smaller.

In the European legislative process, lobbying is a recognised and even a legitimate activity, as reflected in the rather solid consultation tradition. Enthusiasm for participatory lawmaking in the Commission stems from the acknowledged lack of legitimacy through representative democracy. In addition, there is probably a practical reason: the Commission is famously understaffed, creating a clear demand for information from outside.[140]

Opinions differ as to how Better Regulation should primarily affect lobby groups. Some say it means that more must be done for stakeholders and

139 Lobby groups never call themselves lobby groups. Corporate lobby groups like to refer to themselves as 'civil society'. Environmental lobby groups prefer to be known as 'non-governmental organizations' (NGOs). Policy documents tend to use the euphemism 'stakeholders'.

140 De Búrca (1999).

business in particular other say it is the other way around: business must exercise restraint and internalise Better Regulation principles, for instance by justifying their demands more thoroughly. Production of IAs by lobby groups however can undermine the reputation of objectivity of IAs in general. Furthermore Better Regulation rhetoric can be used by business lobby groups who are seeking a privileged status in the IA process on the grounds that the primary goal of IA is enhancing the competitiveness of European businesses. IA represents a new instance of institutionalisation of consultation and thereby provides a new opportunity for those arguing in favour of a 'structural partnership' between the business world and the Institutions.

Involvement in the development of the IA system

> UNICE strongly believes that business representatives and other stakeholders should be part of the network of external experts which is to advise on the quality of impact assessments.[141]

Having demanded more rigorous regulatory analysis for a long time,[142] lobby groups have responded to Commission policy documents on IA in large numbers. Their demands vary from simply 'more impact assessments'[143] to the inclusion of business practitioners in any future panel carrying out independent review and a wish list for certain specific impacts to be included in the Guidelines, e.g. the demands by the European patients and doctors organizations to test all European legislative proposals for detrimental effects on public health.[144] The average wish list of lobby groups – compiled from various contributions to the debate – may look like this:

1. More direct and formal involvement of stakeholders in the evaluation of impact assessment, from the earliest possible moment onwards.
2. 'Self-regulation should always be the preferred option'.[145]
3. Independent review of IAs by outside (economics) experts.

141 UNICE, 'Comments on the Commission Communication A Strategic Review of Better Regulation in the European Union' (Executive Summary), 18 December 2006, 5. Available at http://212.3.246.117/docs/1/PCEIHEEAMLKAIHMOPFCAFAJCPDBN9DWWBG9LI71KM/UNICE/docs/DLS/2006-01809-EN.pdf (last accessed 20 April 2007). See also UNICE position paper of 12 June 2006 in which some further recommendations for rendering the Community impact assessment system more effective are listed.

142 UNICE, *The UNICE Regulatory Report. Releasing Europe's Potential Through Targeted Regulatory Reform* (Brussels, 1995).

143 European Voice (2005).

144 Jet Bruinsma, 'EU-regels toetsen op gezondheid', *NRC Handelsblad* (Rotterdam, 2006).

145 See remarks by representatives of major companies and federations at the Hearing on Better Lawmaking and Better Implementation of EU Legislation at the European Economic and Social Committee (EESC), Brussels, 1 June 2005. Summary of the proceedings available at http://www.eesc.europa.eu/smo/past/past_first/Summary_EN_FIN_r_ces711-2005_pv_en.doc (last accessed 28 May 2007).

An argument that has been put forward to support the latter point is that such a review could be 'an alternative way of getting market expertise into the analysis'.[146] A possible drawback is that when IA reveals information that the Commission otherwise would have to obtain from lobby groups, the lobby groups lose one source of their power.[147]

Involvement in individual IAs

Lobby groups have discovered impact assessment as a way for opposing legislation or influencing its content on both procedural and substantive grounds. An example of the latter is the op-ed by the secretary-general of the European Automobile Manufacturers Association (ACEA) in Dutch newspaper NRC Handelsblad.[148] This piece points directly to an impact assessment by the European Commission – albeit without a clear reference – to support the main argument that loss of jobs as a result of planned emission reductions is no malicious fabrication of the car lobby, as was alleged in an earlier newspaper article. A second example comes from a press release dated 31 August 2006 by the European Organization for Packaging and the Environment (EUROPEN), in which the European Parliament was asked to reconsider the 'potentially damaging'[149] approach towards including something called the '5 step hierarchy':

> The now generally applicable 'Better Regulation' tests commit both the EU and Member States to apply the triple impact assessment; economic, social and environmental. A strict hierarchy is unlikely to be justified under such tests.[150]

This statement can be seen as an attempt to draw impact assessment requirements into the sphere of legal obligations, and so can the next example, which shows how lobby groups use IA for procedural opposition. When the Commission announced on 28 March 2006 a proposal for a regulation aimed at bring-

146 Posner (2001), p. 42.

147 House of Lords 9th report (2005), p. 8 of Minutes of Evidence.

148 I. Hodac, 'Zuinige auto te duur voor EU', *NRC Handelsblad* (Rotterdam, 2007). The impact assessment referred to is not specified, but presumably the impact assessment on 'Results of the review of the Community Strategy to reduce CO2 emissions from passenger cars and light-commercial vehicles', SEC(2007) 60, 7 February 2007 is meant. Some of the claims made in the op-ed are are sustained by the IA (the technology-based solution being the most expensive one) but other are intraceable (that the Commission agrees that the manufacturing of small cars will probably move to Russia).

149 Press Release quoting the managing director of EUROPEN, 31 August 2006. Available at http://www.europen.be/?action=onderdeel&onderdeel=5&titel=News+Room&categorie=1&item=16 (last accessed 15 July 2007).

150 *Ibid*.

ing down the costs of using mobile telephones abroad (roaming),[151] lobby groups were quick to point out the absence of an IA:

> If the Commission continues to pursue the idea of legislation, it should first carry out a full impact assessment. This kind of analysis is a requirement of the Commission's own internal process guidelines.[152]

An impact assessment was produced by the Commission afterwards.[153] Another example of a procedural objection related to IA comes from an AmCham position paper:

> A revision of the Design Protection Directive was proposed in 2004, without any official consultation process. Although an externally contracted impact assessment did include a consultation with industry, the Commission ignored its results and based its proposal on its own internal impact assessment, which had been carried out without any dialogue with the industries concerned.[154]

Another trend in the category of procedural action is for stakeholders to request that impact assessments be carried out in retrospect. In debates on legislation some people argue that even those proposals that were initiated before the stricter rules on impact assessment applied, ought to be subjected to an impact assessment retrospectively, such as in the case of the Markets in Financial Instruments Directive (MiFID).[155] The Software Patents Directive,[156] now famous for being vetoed by the European Parliament, had an informal impact assessment (from before the adoption of the new framework in 2002), but industry representatives have expressed regret at the fact that the impact assessment played no role, specifically referring to the conciliation

151 COM(2006) 382. The regulation has been adopted in the meantime: Regulation (EC) No 717/2007 of the European Parliament and of the Council of 27 June 2007 on roaming on public mobile telephone networks within the Community and amending Directive 2002/21/EC, OJ L 171, 29 June 2007.

152 GSM Association Press Release 2006, 'Further Roaming Regulation is Unnecessary and Potentially Damaging. GSMA calls for a full impact assessment of any EU-wide roaming legislation'. Available at http://www.gsmworld.com/news/press_2006/press06_22.shtml (last accessed 15 July 2007).

153 SEC(2006) 925.

154 AmCham EU, 20 September 2005, Position Paper on Consultation Processes, 4. Available at http://www.eucommittee.be/Pops/2005archive/consultationprocess20092005.pdf (last accessed on 23 November 2006).

155 Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments amending Council Directives 85/611/EEC and 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC, OJ L 145, 30 April 2004, pp. 1–44.

156 COM(2002) 92.

stage.[157] There have also been calls for impact assessments for legislation in second reading, for which Council agreement has already been reached, including the proposals on F-gases and waste shipment.[158]

On the substantive front there is a clear trend to present 'advocacy papers camouflaged as impact assessments'.[159] The best-known example of this is the REACH case (see VI.1) in which the line between 'institutional IAs' and 'private IAs' became blurred, especially because some IAs were financed in a not so transparent way. A quote from a high-profile representative of the corporate lobby illustrates the lack of clarity regarding IA responsibilities.

> [A]t the end of the day some of the impact assessments in relation to chemicals had been funded by the business community which we did not do with any enthusiasm because we did not think it was a thing that we should have to pay, but we came to the view that it was the only way of making sense of the proposals.[160]

Another example of a position paper that the authors have tried to upgrade by calling it an impact assessment is the 'impact assessment template' on the proposed shareholder rights directive[161] sent by the European Policy Forum (EPF) think tank to German Chancellor Merkel 'in order to assist scrutiny by the Council'.[162] Cleverly, the template proposes a framework of how a proper impact assessment should be carried out, while hinting that no legislation is the most appropriate solution.

When lobby groups are reviewing IAs – which they frequently do – there is a distinction between stakeholders identifying a material weakness or error in the IA and disagreeing with the proposal on political grounds. The boundaries between these two positions can easily become blurred, raising questions such as: is there a way for the co-legislators to make this distinction? Or is there perhaps a way to identify 'misuse' of IA procedure? And perhaps most importantly: can IA provide an incentive to report truthfully?

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157 Mr John Cridland, Deputy Director-General of the Confederation of British Industry, during his examination by the European Union Committee of the House of Lords. House of Lords 9th report (2005).

158 COM(2005) 462.

159 Radaelli (2007), 200.

160 Mr John Cridland, Deputy Director-General, Confederation of British Industry (CBI), House of Lords 9th report (2005).

161 The directive has been adopted on 11 July 2007. Directive 2007/36/EC of the European Parliament and of the Council of 11 July 2007 on the exercise of certain rights of shareholders in listed companies, OJ L 184, 14 July 2007, pp. 17–24.

162 Http://www.manifest.co.uk/manifest_i/2007/0702Feb/0702standards/0702standardsshareholderrights.htm (last accessed 18 February 2007).

Towards a self-regulatory code?

Lobby groups have certainly discovered the discourse and are fully exploiting the normative force of IA. Yet the most interesting angle from which to discuss the topic of lobby groups and IA is the repeated call to tie the benefits that lobby groups get from the requirements for the Institutions to produce IAs to certain expectations for their conduct when using IAs. As MEPs McCarthy and Frassoni put it in a newspaper article

> [s]takeholders must also embrace the Better Regulation agenda and justify their demands for substantial changes or amendments. They should exercise restraint in using the legislative process, in the Parliament, to achieve an advantage over their competitors.[163]

Here the proposal put forward by representatives of the European Commission to encourage all lobby groups listed in the CONECCS database a register to adhere to a common code of conduct which is administered by the sector itself, could be a solution.[164] Such a self-regulatory mechanism could also include 'a system of monitoring and sanctions in case of incorrect registration and/or breach of the code of conduct' with possibly 'a new, inclusive external watchdog to monitor compliance'.[165] There is no reason why guidance on how to use IA could not be included.

V.7 THIRD COUNTRY ACTORS

> [T]he adoption of Better Regulation in Europe can itself create a common language and platform for greater transatlantic communication and collaboration about regulatory policy.[166]

The EU Better Regulation movement has never been a self-standing force. A process of international convergence of best practices in regulatory quality management is taking place. Some see this as spontaneous international convergence, others emphasize the conscious aspects of the process and conceptualise it as an instance of transnational 'legal borrowing',[167] particularly from the US. The EU's recent Better Regulation policy, and especially the

163 McCarthy and Frassoni (2005) (contribution MEP Arlene McCarthy).
164 Speech by Siim Kallas, Vice-President of the European Commission, responsible for Administrative Affairs, Audit and Anti-Fraud, 'Transparency restores confidence in Europe', European Policy Institutes Network, Centre of European Policy Studies, Brussels, 20 October 2005.
165 Press release, 'Greater transparency in EU affairs will strengthen legitimacy', IP/06/562, 3 May 2006.
166 European Policy Centre (2005), p. 12.
167 Wiener (2006), 518.

element of coming up with guidelines on consultation and IA, has been interpreted by some as a convergence towards the American approach of an Administrative Procedures Act which regulates the way regulations are issued.[168] Since regulatory cooperation with the US is much more developed than similar cooperative dialogues related to regulation with other third country actors, this section will only deal with the US.

V.7.1 EU-US regulatory cooperation on IA

It has been suggested that one way to handle regulatory differences between the US and the EU (causing obstacles to trade, etc.) is to mutually recognise regulation or to achieve some degree of convergence.[169] Usually this cooperation on the substance of rules is what is meant by 'regulatory cooperation'. But on occasion the debate is extended to the issue of whether there should also be coordination of regulatory quality policy. It has been suggested that these transnational dialogues on regulatory reform policies – so on the meta-level rather than on substantive regulatory issues – are a way of handling transnational regulatory conflicts of a substantive nature. These dialogues would then – at least partially – have to be about shared substantive standards of impact assessment. This seems to be one bridge too far for the EU-US regulatory cooperation as it currently stands.

The US government has been one of the most enthusiastic proponents of EU Better Regulation.[170] At the US-EU summit in Washington DC on 20 June 2005, Better Regulation was a topic of discussion and the next summit is expected to call for closer cooperation, especially on impact assessment.[171] On 17-18 March 2005 a conference was held on 'Better Regulation: The EU and the Transatlantic Dialogue' co-sponsored by the European Policy Centre, the European Commission, and the US Mission to the EU. It had as its unsurprising conclusion that

> [t]he European Union's institutions have made impressive progress on the Better Regulation initiative in recent years, but it is vital to maintain this, not least because unnecessary red tape generates enormous costs.[172]

The US Mission to the European Union in Brussels also organized a seminar entitled 'Better Regulation: The EU and the Transatlantic Dialogue' which brought 20 regulatory representatives from the new EU member states to Brussels for a day of training in EU approaches to regulation, followed by a

168 A senior Commission official, quoted by Kwast and Simon (2005).
169 Löfstedt (2004); Guidelines for EU-US regulatory cooperation (2002).
170 A. Renda, 'Getting EU impact assessment right', European Voice (Brussels, 2005).
171 Löfstedt (2007).
172 European Policy Centre (2005).

second day of comparative approaches to regulation which focuses on how the United States approaches regulation. John Graham, a professor who was at the time leading the Office of Regulatory Affairs (OIRA), was heavily involved in US-sponsored activities on Better Regulation in Brussels. A further personal impetus to EU-US cooperation on regulatory policy came from C. Boyden Gray, the US ambassador to the EU in Brussels, who is said to take a special interest in Better Regulation.[173]

Whether EU civil servants will benefit from American training is doubtful however, as the US impact assessment system (the American term is 'regulatory impact analysis') is very different from the EU system, although along different lines than commonly believed. True, the American approach puts more emphasis on quantification, but the legitimacy of the use of cost-benefit analysis (CBA)[174] as a basis for regulatory decisions continues to be discussed in academic literature. In practice though, a consensus has developed that the use of CBA is defensible, even if only because there are few alternatives for rational policy-making.[175] The use of CBA is supported by both major political parties. President Clinton watered down somewhat President Reagan's Executive Order (EO) 12291 when his new EO 12866 replaced the requirement that benefits *outweigh* the costs of regulation with the requirement that benefits *justify* the costs.

State of play

Against this background it is understandable that the cooperation on impact assessment at the moment remains limited. The European Commission has developed guidelines for EU-US regulatory cooperation and transparency in 2002, which were politically endorsed at the EU-US summit. In 2005 the Commission issued a Communication on 'A stronger EU-US Partnership and a more open market for the 21st century' which suggested a reinforced approach to regulatory policy cooperation.

> A reinforced approach should comprise:
> · enhanced upstream cooperation, including the following key elements:
> (a) timely exchange of the annual work programmes of the Commission and US regulators,
> (b) a 'regulators' hotline' to be used where one party requests to be consulted on new regulatory initiatives being planned by the other which have the potential to affect its important interests,
> (c) identification of sectors where cooperation has the greatest chance of delivering increased economic benefits,

173 Löfstedt (2007).
174 Often called 'BCA' in the US.
175 Wiener (2006), 463.

(d) consultation in international standard-setting bodies at the development stage of new standards or policy initiatives,
(e) encouragement of proportionate assessments of the economic, social and environmental impacts beyond the borders of the respective parties,
(f) exchange and development of best practice in terms of risk analysis regarding the protection of consumers and the environment, taking into account the precautionary principle,
(g) additional measures to promote improved understanding of each other's regulatory practices and more effective and consistent application of regulatory approaches and tools. This would include exchange of best general regulatory practice, addressing for example

- transparency provisions and public consultation;
- recognition of equivalence where regulations and standards, while different, provide equivalent levels of protection and quality;
- development of common standards, where appropriate.[176]

The EU and the US evidently have no formal say in each other's impact assessment processes and are not obliged to specifically take into account impacts on each others' economic, social and environmental system. Calls for cooperation on concrete IAs in order to improve the economic analysis proved one bridge too far. The current wording is that each entity is encouraged to carry out 'proportionate assessments of the economic, social and environmental impacts beyond the borders of the respective parties' but that does not exceed the general obligation in the Commission's guidelines to take into account impacts outside the EU.

Restraint at the policy level, does not preclude the US authorities from trying to influence the content of individual IAs on occasion. An example of this is the REACH IA procedure (see VI.1) in which the US government argued that quantification was insufficient. This kind of lobbying by third country governments is not necessarily lacking legitimacy, as it can also be seen as being in line with the Commission's overall policy for entering into dialogues with stakeholders. However, it is important to keep in mind that we are dealing with a very special type of stakeholder.

V.8 Concluding remarks

IA is becoming part of the common normative environment of all of the actors discussed in this chapter. Many co-actors are seeking privileged access to the IA process by highlighting one of the values (subsidiarity, competitiveness) that IA is supposed to address. The question to what extent other actors than Commission, Parliament and Council are, can and should be involved crucially

176 Communication from the Commission, COM(2005) 196 final, Brussels, 18 May 2005, 'A stronger EU-US Partnership and a more open market for the 21st century', p. 7.

hinges on the relationship between EU IA and consultation for some actors (advisory bodies, lobby groups, citizens, third country actors), on the relationship between IA and legal standards for lawmaking (Court of Justice and Court of Auditors), IA and subsidiarity (national bodies) or IA and accountability (comitology). For most co-actors, the negotiations on the extent of their involvement in the IA procedure are still ongoing. This involvement needs to be balanced against the institutional risk that too much involvement of these advisory bodies comes down to effectively sharing the right of initiative with the Commission.

VI Case-studies I: diverging uses of IA in environmental lawmaking

The case study template

The case-studies follow a somewhat artificial template of a three-tiered analysis (process, content and use of IA). Artificial, because the point repeatedly made throughout this thesis is that the reality of IA almost never fits the model of one uncontested IA document that was prepared alongside a dedicated consultation process and then goes on to be 'used' in the legislative process. As some of the cases presented below (REACH, pre-packaging) show, the process of assessing impacts often continues during the 'usage phase'. Furthermore, the results of the IA are not always laid down in one particular document; the content of the IA can be selective, it can overlap with other documents including the proposal itself and other documents can appear which compete with the 'original Commission IA' which in itself can be subject to revision. However, this structure is necessary in order to be able to compare the case studies later on (see VIII.1). The goal of these case studies is not to evaluate the respective IAs. The aim is rather to see what kind of weight IA can potentially carry in European lawmaking by analysing process, content and use for each case and the interaction of these, using the theoretical models set out in section II.3.

Environmental lawmaking

EU environmental regulatory processes are characterised by the following three elements:

1) although not among the original competencies attributed by the Treaty of Rome, environmental regulation nowadays accounts for a very high number of European laws;[1]
2) the legal basis for EU action remains usually uncontested, (although there have been some recent quarrels relating to the use of criminal sanctions);[2]
3) the stakeholder positions are rather well-defined along bipolar lines;
4) there is longstanding experience with measuring policy impacts.

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1 A. Lenschow, 'Environmental Policy in the European Union: Bridging Policy, Politics and Polity Dimensions', in *Handbook of European Union Politics*, K.E. Jorgensen, M.A. Pollack, and B. Rosamond (eds) (London, Sage, 2006), p. 415.

2 *Commission v. Council*, Case No. C-176/03 [2005] ECR I-7879.

The two case studies presented in this chapter – one on the much debated new chemicals regulation REACH[3] and one on the clean air strategy CAFE[4] – are similar in many respects. Both are pieces of ambitious environmental regulation and are associated with the large-scale costs and benefits typical for environmental policies. From the perspective of IA research it is also interesting to note that each case has been quoted extensively both as an example of good practice and as an example of bad practice. But there are important differences too. REACH is a targeted regulation, whereas CAFE represents a broad strategy. The latter case is in an area were a lot of scientific assessment has been done over many years; the former case is all about the problem of lack of scientific evidence.

VI.1 REACH: WHEN IA MATURED?

> I think impact assessments came of age with the REACH proposals on chemicals but, my word, it was a painful process.[5]

VI.1.1 Background in brief

REACH (Registration, Evaluation and Authorization of Chemicals) is the main example of a legislative dossier in which the estimation of costs and benefits played a major role in the legislative debates coupled with a discussion on which role impact assessment *should* play. The REACH proposal is about the obligatory testing for health-related and environmental effects of all so-called 'existing' chemicals in the European market. Before REACH was adopted these 'existing' chemicals were subject to a much lighter regulatory regime than the 'new' chemicals brought on the market from 1981 onwards. Not only was there a fundamental lack of information on chemicals introduced before 1981, the different sets of rules applied to chemicals depending on the time of their first introduction also meant that there was no level playing field for businesses involved. The so-called 'data gap', meaning the difference between the demand for information needed to put in place an adequate regulatory regime and the supply of that information is a common problem in the regulation of the

3 Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, OJ L 396, 30 December 2006, pp. 850–856.

4 COM(2005) 446 final.

5 Mr John Cridland, Deputy Director-General, Confederation of British Industry (CBI), see House of Lords 9th report (2005).

chemicals sector worldwide.[6] The solution put forward by REACH involves shifting the responsibility for the safety of chemicals to the chemicals industry. They must register the 30,000 chemicals that are produced or imported at a quantity of one tonne or more per year with the newly established EU Chemicals Agency and provide information on the properties of the chemical. REACH also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives are known to exist.

The proposal had been debated intensely over the past few years and has acquired a reputation as 'the most extensively analysed draft legislation in history'.[7] Not only the REACH proposal has been assessed extensively, the assessments of REACH themselves have been subject to intensive scrutiny by commentators. Some have even tied their evaluation of the Better Regulation strategy to the performance of this dossier. 'REACH is no doubt the critical test case of whether the Union is capable of giving itself "Better Regulation"', Pelkmans stated in a highly critical presentation for the hearing of the European Parliament on REACH.[8] Even so, it should be noted that REACH is a rather exceptional case in terms of ambition, complexity and controversy. This chapter therefore tells a story about what *can* happen to the use of impact assessment, but – due to the exceptional circumstances surrounding REACH – it should certainly not be taken as *the* story of impact assessment in EU lawmaking.

The story to be told below is often a technical and complicated one, involving a multitude of actors and impact assessments. It becomes a lot easier to read and understand if one grasps the great regulatory bargain that lies at the heart of this case. REACH became possible because there was a general acceptance that the regulatory framework in place penalised new chemicals by requiring a lot of safety information from very low tonnages, compared to very little information requirements for chemicals produced before 1981. On the basis of this acknowledgement by all stakeholders a huge compromise was struck. Environmental NGOs accepted some deregulation of the sector overall by means of increasing the tonnage threshold for the information requirements.[9] Corporate stakeholders in return went along with the new system, albeit grudgingly.

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6 Applegate (2006).

7 WWF European Policy Office (Tony Long), 'Fair chemicals provision for EU is within Reach', Financial Times (2005).

8 J. Pelkmans, 'REACH: Better Regulation for Europe?', Presentation for the Hearing of the European Parliament on REACH, 19 January 2005 (revised and corrected version) (Brussels, 2005).

9 This analysis of the situation is inspired by the remarks of a senior campaigner of environmental NGO Friends of the Earth giving evidence before the Environmental Audit Committee of the House of Commons in the context of a report on the functioning of impact assessment.

VI.1.2 The IA process

The run-up to the extended IA

The debate about reforming the EU regulatory system for chemicals began as early as April 1998, when the informal Environment Council expressed concerns about the chemical regulatory system. In November of the same year the European Commission published a report on the functioning of the four main chemicals regulatory instruments.[10] In June 1999 the Environment Council formally concluded that a new approach to chemicals regulation was needed, and called on the Commission to submit the policy document outlining a new chemicals strategy by the end of the year 2000.[11] In February 2001 the Commission published a White Paper proposing a new system called 'REACH' (Registration, Evaluation and Authorization of Chemicals).[12] On the subject of this White Paper a stakeholder debate was organized, marking the start of an extraordinarily intensive lobbying campaign. The preliminary REACH proposal received support in the Environment Council of June 2001 and in the European Parliament in November 2001.[13] A joint team from DG Environment and DG Enterprise started to draft the full REACH proposal. In the winter of 2001-2002 technical working groups with contributions from stakeholders were being organized by the Commission for the purpose of securing broad industry support for such a large-scale proposal. On 21 May 2002 the Commission organized a stakeholder debate on the Business Impact of REACH,[14] at which a draft business impact assessment (BIA) was presented and discussed; this impact assessment was subsequently published in June of that year.[15]

REACH was not originally included in the list compiled for the IA pilot phase, which contained mostly relatively uncontroversial proposals items. However, since DG Enterprise had already carried out impact analysis on REACH, the Director-General of DG Environment proposed to jointly carry out a 'proper' IA.[16] Thus, the IA became a co-production of DG Environment and

10 SEC(1998) 1986 final.

11 Conclusions of the Environment Council, 26 June 1999, available at http://ec.europa.eu/enterprise/reach/docs/whitepaper/council-11265-99.pdf (last accessed 18 July 2007).

12 COM (2001) 88.

13 Conclusions of the Environment Council, 8 June 2001, available at http://register.consilium.eu.int/pdf/en/01/st09/09857en1.pdf (last accessed 18 July 2007); European Parliament Resolution on the Commission White Paper on Strategy for a future Chemicals Policy, OJ C140E, 13 June 2002.

14 EC Conference minutes (2002).

15 RPA and Statistics Sweden, 'Assessment of the business impact of new regulations in the chemicals sector (final report)', Prepared for European Commission Enterprise Directorate-General (Brussels, 2002). A revised version was published in 2003 and is available at http://ec.europa.eu/enterprise/reach/docs/reach/rev_bia-2003_10_29.pdf (last accessed 18 July 2007).

16 Interview Commission official A.

DG Enterprise with the latter being responsible for the in-depth econometric modelling. In summer 2003 an internet consultation on the full draft REACH text was held. Perhaps the fact that there were 6400 reactions to the consultation[17] was a telling sign; the impact assessment procedure that was to follow would turn out to be an initiation ritual of sorts for the Commission IA system.

Even before the Commission had finalised its proposal, France, Germany and the UK – apparently influenced by 'private' impact assessment studies predicting hugely detrimental effects to the economies of these countries – sent a letter to the Commission in September 2003, warning about the heavy impact on the industry. As a consequence of this joint intervention by the three large Member States the Commission amended its draft proposal. Reports vary however as to whether the last-minute changes amounted to a 'radical change'[18] or involved only minor changes, as the main direction of the proposal had been fixed by then.[19]

The official REACH proposal[20] was published by the European Commission with an 'extended impact assessment'[21] – as it was then still called – on 29 October 2003, so after five years of debate. This impact assessment will be referred to as the 'original IA', as it was carried out in accordance with the (pilot version of) new formal integrated impact assessment framework.

The flood of impact assessments

Once the impact assessment report was published, predicting high but not outrageous costs (see VI.1.3), stakeholders and especially the industry lobby groups started rallying against the extended impact assessment by the Commission as the final and comprehensive study. In this great lobby cacophony many stakeholders had their own IAs ready – sometimes even prepared in anticipation of the Commission IA – to be used as ammunition in the battle for the numbers on the basis of which the legislative decision would be made.[22] There was a consensus among all actors that a regulation such as REACH would incur considerable costs for businesses, but estimates of how high those costs would be differed enormously. The estimates of the benefits varied even more. A real problem in the production and presentation of these 'private IAs' was that many were continuously being overtaken by developments in the lawmaking

17 I. Schörling, *REACH – The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why?*, report for the Greens/European Free Alliance (Brussels, 2004), p. 137.
18 European Environment and Sustainable Development Advisory Councils (2006), p. 14.
19 Interview national official A.
20 COM(2003) 644 final.
21 SEC(2003) 1171.
22 This emerged also during the workshop on impact assessment of REACH which the Commission organized on 21 November 2003.

process, analysing elements of policy options that were no longer on the table.[23]

One main point emerging from the many publications on REACH by environmentalist groups is that – in hindsight at least – they did not favour further impact assessments and were keen to stay as close as possible to the original Commission proposal and the accompanying impact assessment. They condemned IAs produced by corporate lobby groups on substantive as well as procedural grounds. In their main report on the use of impact assessments in the REACH decision making process they commented also on the many IA studies commissioned by the industry:

> After publication of the White Paper, industry produced a number of hugely exaggerated impact assessment studies (notable by consultants Arthur D. Little and Mercer), which have been condemned many times by economists, but have been politically very effective in generating the idea that REACH will be hugely burdensome.[24]

This section focuses on the difficulties with reaching agreement on the appropriate procedure for arriving at the results that can serve as a basis for legislative decision-making, whereas section VI.1.3 analyses the content of the Commission IA and section VI.1.4 deals with the contention surrounding the issue of how to take these results into account in a legitimate manner.

Mediation attempt I: the Memorandum of Understanding

Corporate lobby groups, particularly CEFIC (European Chemicals Industry Council) and UNICE (European Industrial Federation) started exerting pressure on DG Environment and DG Enterprise to review the initial impact assessment. After initial reluctance on the part of the Commission[25] and concerns about delaying the legislative process[26] preparations were made to set a new IA process in motion.

> As a result of the discussion with stakeholders, the Commission agreed to undertake further impact assessment work, complementary to its extended impact assessment.[27]

23 Interview Commission official A.
24 Schörling (2004), p. 121.
25 Mr John Cridland, Deputy Director-General, Confederation of British Industry (CBI), see House of Lords 9th report (2005).
26 Schörling (2004), p. 101.
27 European Commission, DG Environment website on REACH http://ec.europa.eu/environment/chemicals/background/impact_assessment_intro.htm (last accessed 25 May 2007).

Negotiations finally led to agreement on further impact assessment of REACH laid down in a Memorandum of Understanding (MoU) containing the commitment to 'provide a framework for the efficient undertaking of further investigations on business impacts of REACH' on 3 March 2004. The MoU was concluded between four parties only (CEFIC, UNICE, DG Environment and DG Enterprise) but in order to lend the exercise greater legitimacy the 'REACH High Level Group on Further Work on Impact Assessment' was established to oversee the work. The High Level group consisted of a broader group of stakeholders (industry, trade unions, environmental and consumer NGO's) and representatives from Council and Parliament. At the operational level a Working Group was also established with the same balanced composition and charged with the task of monitoring the progress of the studies. At the fourth meeting of the Working Group, on 14 July 2004, UNICE and CEFIC were given the go-ahead to sign their contract with KPMG to start the study. Through case studies, factual evidence on how REACH affects businesses was to be collected, especially with regard to the mass withdrawal of chemicals predicted by industry. Another study was to be undertaken by the European Commission's 'Institute of Prospective Technological Studies' (IPTS) on the effects of REACH on (prospective) new Member States. Between May 2004 and April 2005 the working group supervised the two additional impact assessments, mainly discussing the methodology.

Whereas the initiative seemed to have all the ingredients for contributing to the deliberative quality of the lawmaking procedure (pragmatic, participative and pluralistic, see II.2.6) the process failed to remain inclusive in the eyes of the non-corporate stakeholders. The Commission contended that the whole IA process was transparent, but the environmental lobby – represented in the working group by the WWF and the European Environmental Bureau (EEB) – did not agree. In a briefing on REACH impact assessment the two organizations wrote:

> Despite using a biased methodology (which we do not support) – systematically excluding business benefits and using exaggerated testing cost scenarios, up to 4 times higher than Commission assumptions – KPMG did not find that important chemicals would be withdrawn for economic reasons.[28]

WWF and EEB have even issued a statement saying that they could not support the additional REACH impact assessment by KPMG, citing 'major deficiencies in both the methodology and transparency of the process' as their reasons. More specifically WWF and EEB objected to the fact that the non-business members of the working group did not have access to 'key parts of the study',

28 European Environmental Bureau and WWF DetoX Campaign, 'REACH impact assessments. Assessing EU Environmental Policy Impacts. A Critical Evaluation of Impact Assessments carried out for Europe's chemical policy reform (REACH)' (Brussels, 2005).

such as KPMG interview materials, but that they would 'nevertheless be expected to endorse conclusions drawn from them'. Also their suggestion to incorporate business benefits from REACH, such as safety at work, in the new study was not adopted, leading EEB and WWF to conclude that 'the methodology of the study is biased towards industry interests'. The statement identified '[achieving] a common understanding of the impacts on business from REACH' as the key aim of the working group and said that this aim was unlikely to be achieved 'if the methodological and transparency issues are not resolved'. WWF and EEB decided to remain involved in the impact assessment working group 'in order to be able to follow the process'. The European Commission issued a note on the studies undertaken in the framework of the Memorandum of Understanding in which the fairness of the process was defended, stating among other things that third-party verification of the KPMG results, carried out by the two expert advisers, concluded that although all verified data were presented anonymously, the KPMG team had indeed derived the findings presented in the sector workshops from the information documented in the spreadsheets.[29] This failed to convince WWF and EEB to endorse the additional impact assessment, even after a few meetings were held between the environmental groups and the business groups, as well as KPMG. Corporate stakeholders also voiced their criticism on certain procedural aspects, repeatedly stating that IA is a task for the Commission and industry should not have to pay for it, but should have sufficient opportunity for scrutiny of IAs. These statements suggest that industry paid for the further IA work, but the issue of financing remains a bit blurry. The MoU cryptically states under the heading 'Financing of the Studies':

> The industry side, as well as the Commission services, agree to carry out the studies on the issues indicated in section 3.[30]

It seems that raising the stakes of this additional impact assessment ('achieving a common understanding of the impacts') has put procedural issues such as transparency and financing in the spotlight.

Mediation attempt II: the Dutch Presidency workshop

A second attempt to mediate between different appraisals of the impacts of REACH was initiated by the Dutch Presidency of the European Union. On 25-27 October 2004 it organized a workshop on the REACH impact assessments –

29 European Commission, 'Note on the studies undertaken in the framework of the Memorandum of Understanding on Further Work concerning the Impact Assessment of REACH'. See http://www.cefic.org/files/Publications/Commission_conclusions_IA.pdf (last accessed 15 July 2007).

30 Memorandum of Understanding (2004), p. 4.

according to the summary report there were 36 impact assessments available at the time[31] – for Council experts in order to 'bring together the results of the studies already available and to consider the lessons to be drawn from them'.[32] Representatives from the EP and Commission were also present at the event.

The Dutch EU Presidency in a compilation of the impact assessments carried out until then, mediated between their varying outcome by proposing to take an estimated cost of 4 billion euros as the starting point in subsequent legislative debates.[33] The workshop focused on the question how to maximize cost effectiveness for industry and in particular SMEs[34] (e.g. by promoting cooperation between firms) as a way out of the deadlock that had arisen around the estimates of the direct and indirect costs to industry and the benefits of the proposal.[35] In its conclusions the workshop did not call for further impact assessment work on REACH. Instead, the 'general feeling that future research on the impact of REACH should also address the workability of REACH for industry and the competent authorities' was expressed.[36] It was also stated that '[a]ny major proposals for amending the Commission's REACH proposal should take costs and benefits into consideration'.[37] For some this workshop was an example of appropriate space for business input to others it was just a prologue to the negotiations in Council. It is here that the foundation was firmly established for the approach that came to increasingly dominate this dossier, namely a pragmatic focus on cost-effectiveness at the expense of cost-benefit analysis of various options.

US involvement: IA as 'non-paper'?

The REACH proposal stirred up one of the biggest transatlantic regulatory clashes in years.[38] After some early concern for the implications of REACH for US businesses, the US Trade Representative circulated a so-called 'non-paper' (meaning that no public body takes direct responsibility for it) in 2002 which argued that REACH raised important concerns regarding compliance with the

31 REACH overview report (2004).
32 Conclusions REACH IA Workshop (2004).
33 This figure is nearly 2x the previous official EU Commission estimate of 2.3 billion euros. SEC(2003) 1171.
34 ECORYS & OpdenKamp Adviesgroep, 'The impact of REACH. Overview of 36 studies on the impact of the new EU chemicals policy (REACH) on society and business', workshop REACH Impact Assessment, 25-27 October 2004 (The Hague, 2004), p. 7.
35 Netherlands Presidency of the Council of the European Union, 'Conclusions and recommendations of Workshop on REACH Impact Assessments' (The Hague, 2004), p. 2.
36 ECORYS & OpdenKamp Adviesgroep (2004), p. 2.
37 *Ibid.*, p. 7.
38 An example of another big clash over the content of regulation is the dispute on genetically modified food regulation.

WTO's 'least trade restrictive' requirement'.[39] The content of this paper was very close to an impact study by the American Chemistry Council.[40] In early spring 2003 Secretary of State Colin Powell also attempted to directly intervene in the decision-making process by sending a diplomatic cable to EU member states about the REACH proposal. This document contained a long list of arguments against the REACH proposal as it stood then, including potential harmful and even illegal trade implications. The highly critical Waxman report – an investigative report prepared by the staff of the US House of Representatives Committee on Government Reform – claimed that these arguments almost literally reiterated the industry concerns.[41] One of the arguments directly concerned the use of impact assessment. According to the Waxman report the industry stated in an e-mail:

> The EU should complete a cost-benefit analysis of the draft legislation, with particular emphasis on the effect on small and medium enterprises and downstream users of chemical products.

Powell wrote in his diplomatic cable:

> Before finalizing its proposal, we urge the [European Commission] to conduct a complete impact assessment, including the impacts on downstream users and future investment and innovations.

There is also a public document containing the US Government's concerns regarding the REACH proposal. They are made in the context of a WTO Technical Barriers to Trade (TBT) notification by the Commission and quotes extensively from the Commission impact assessment, comparing it to other studies (mainly the ones by Mercer and Arthur D. Little).[42] The Waxman report claimed that the lobby by the US administration had an influence on the European Commission decision to present a new impact assessment.[43]

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39 According to the Transatlantic Consumer Dialogue, see http://www.tacd.org/docs/?id=253 (last accessed 15 July 2007).

40 Schörling (2004), p. 113.

41 Pelkmans (2005).

42 US Government comments on the EU's REACH, submitted to the World Trade Organization's Technical Barriers to Trade Committee: Comments of the United States on Notification G/TBT/N/EEC/52 Regarding European Commission Regulation COM(2003) 644, 21 June 2004. Available at http://www.citizen.org/documents/US_TBT_Comments.pdf (last accessed 15 July 2007). Previously, the same document was available at the website of the United States Mission to the European Union (http://www.useu.be/Categories/Evironment/June2204USREACHComments.html), but the link no longer works.

43 Waxman report, 'A special interest case study: The Chemical Industry, the Bush Administration, and European Efforts to Regulate Chemicals', US House of Representatives Committee on Government Reform – Minority Staff Special Investigations Division (Washington DC, 2004), p. 14.

VI.1.3 The IA content

This section discusses the content of the 'original IA', the results of the assessment as laid down in the IA report that was published and distributed alongside the Commission's 2003 proposal. With its 33 pages it comes close to the ideal length promoted by the 2005 Guidelines, although it should be noted that the REACH IA was conducted during the pilot phase during which an earlier and less comprehensive version of the Guidelines was applicable.

The REACH IA lists as many as seven objectives: human health and environment (main objective I), the competitiveness of the EU chemicals industry (main objective II), prevention of fragmentation of the internal market, increased transparency of the regulatory regime, integration with international efforts, discouragement of animal testing and WTO conformity.[44] Different objectives relate to different instruments all included in REACH, raising the question of whether there should not have been separate IAs for each part.[45] This degree of precision is typical for the REACH IA; section by section the impression is reinforced that this is an IA made in a very late stage of the policy development process. Indeed, some fundamental choices were already made at the stage of the White Paper. However, impact assessment carried out at the time of the White Paper has been criticized for being 'limited in that it was based on the White Paper, which did not give sufficient detail for a comprehensive assessment', confirming that the frequent observation that it is hard to get impact assessment right.

Since the proposed REACH regulation would replace many different existing directives subsidiarity was not considered an issue. With the shift of the burden of proof on chemicals properties causing a lot of additional costs for industry, proportionality is an undeniable issue however. The IA remains vague on this point, arguing merely that 'great care has been taken to ensure that the new legislation is not excessive in terms of scope, costs and administrative burden' by opting for a tiered approach for certain classes of chemical substances.[46]

When addressing policy options the IA refers to the 'wide measure of consensus on the need for reform' and the preference of the Council and the Parliament for 'development of more effective mechanisms and procedures which would place a greater onus on industry to make available information on the hazards, risks, and risk reduction measures for chemicals currently in use, and would create greater confidence that dangerous substances were being used safely'.[47] The use of 'alternative, more flexible, policy instruments such

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44 Jacques Pelkmans during a presentation on the REACH IA at the CEPS conference "Impact Assessment in the EU, taking stock and looking forwards" on 23 January 2006 in Brussels proclaimed that seven objectives are too many for an economist to handle.

45 As is often done in the UK, see for instance the RIAs prepared in 2005 for the Violent Crime Reduction Bill.

46 SEC(2003) 1171, p. 5.

47 *Ibid.*, p. 4.

as co-regulation or self-regulation' was ruled out because '[c]hemicals is an area of Community activity that should be governed by full harmonisation because of the need to preserve the integrity of the internal market, to avoid trade distortions and conflicts and to guarantee a high level of protection of health and the environment'.[48] This kind of circular argument that presents objectives (preserving the integrity of the internal market, avoiding trade distortions and guaranteeing a high level of protection of health and the environment) as the solution rather than as the benchmark for assessing impacts of various options, is a common pitfall for IA. Pelkmans wrote on this matter:

> After all, a RIA cannot handle unclear or purposefully ambiguous objectives. One, among several, reason(s) why the RIA process has failed to deliver in REACH is that the question of objectives, hence by definition the societal benefits of why the EU legislates in the first place, has not been resolved.[49]

In this case, a complicating factor for performing impact assessment is that there is a sharp divide into two stages of regulation. The first stage is entirely about the collection of information on the properties of chemicals produced at a certain quantity. In this initial stage the costs are high, whereas the expected benefits will only materialise in stage two, when the newly established Chemicals Agency will go on to use the collected data to perform risk management. One of the challenges for IA when assessing this type of legislation is that in the long term the benefits are bound to exceed the costs.[50] However the short term, direct costs – the BIA prepared earlier was used as a basis for calculating these – are considerable and to be borne by specific stakeholders. To complicate things further, the benefits can only be reliably calculated once the new information is available. In calculating the costs the issue of substitution was the key. How many substances will be withdrawn altogether because the testing costs no longer make it profitable for them to be produced? It matters greatly how elastic this is estimated to be. Then the knock-on effects of withdrawal need to be taken into account: how high are the additional costs caused because the chemical supply chain needs to be adapted if an existing chemical is withdrawn? Finally, the health effects are expected to take place more downstream – so in the industries using the chemicals – as the chemicals industry itself already has in place stringent health and safety measures. This means that those carrying the heaviest cost will not be able to reap the benefits at a later point in time. The effects on downstream users were among the hardest to assess,[51] but DG Enterprise in the end came

48 *Ibid.*, p. 5.
49 Pelkmans (2005), p. 2.
50 The model used for calculating the direct costs is the Dixit and Stiglitz model of monopolistic competition with economies of scale.
51 Interview Commission official A.

up with a microeconomic model which predicted that the majority of the costs of testing and registration would be passed on to downstream users.

The Commission tried to overcome these obstacles by looking at marginal changes of cost-effectiveness within the costs. The direct costs for the chemicals industry were calculated at around € 2.3 billion (range € 1.9 – € 3.2 billion) over 11 years of implementation depending on the level of substitution required. The direct costs are separated out into categories and is accompanied by a table showing the net present value of various cost saving measures. The REACH IA was also one of the first to address administrative burdens as a separate category, thus anticipating the later changes to the Commission's IA framework (see III.5.1). With impacts on other industries (when costs were passed on to downstream users) the total cost to industry is predicted to be € 2.8 billion to € 5.2 billion.

The pragmatic focus on cost-effectiveness fits with the fact that real policy alternatives are no longer being considered. However, it also led to accusations from different side that benefits were being ignored. The one benefit that was really quantified in the Commission IA, the reduction in costs for new substances below 1 tonne, is incorporated into the table of direct costs, causing a reduction of € 100 million. Although this choice is understandable in a cost-focussed debate, it also disperses attempts to assess the benefits in such a way that a similar overview of benefits as exists for costs could facilitate the search for a balanced regulatory regime for chemicals. The direct benefits are discussed in a loose, qualitative way straight after the table with the direct costs, whereas the indirect benefits, those to health and the environment are discussed in a separate chapter. Although data to reliably calculate, estimate or even predict health benefits of REACH are lacking, the Commission provided a 'back of envelope' calculation, based on moderate assumptions that 1% of diseases are due to chemicals and 10% of this figure is tackled by REACH, that total health benefits could be in the region of € 50 billion over 30 years. The IA points out expressly that this number is not intended as an estimate, but rather as an illustration of the potential scale of the health benefits.[52] On the environmental side, benefits are stated to be even more difficult to assess, but a list of examples of possible positive environmental impacts is provided. The decision to include these illustrations in the IA in order to paint a rough picture of the benefits was an explicit one taken at the highest level.[53]

The view of the environmental lobby groups – of which EEB and WWF were the most visible in the process – is adequately represented by the following statement from a letter by WWF Brussels:

52 SEC(2003) 1171, p. 31.
53 Interview Commission official A.

> REACH has been subject to more impact assessments than any other piece of European legislation in history. Many of these assessments have been fundamentally flawed, lacking in understanding of REACH, chemicals regulation and economics.

To environmentalists the REACH case is exemplary for the tendency that over the last few years Better Regulation increasingly focussed on the cost of regulation to business rather than on clarifying regulatory objectives and doing whatever is necessary to achieve those.[54] Trade unions have largely sided with the environmentalists, putting forward arguments relating to health and safety in the workplace.

The chemicals industry took the view that the Commission IA relies on wrong assumptions. Mr John Cridland, Deputy Director-General of the Confederation of British Industry during his examination by the European Union Committee of the House of Lords paraphrased the complaints by industry about the original Commission impact assessment in the following way:

> There is a whole series of questions of assumption about how you have reached these costs and these are really up for challenge.

After the results of the new IA resulting from the MoU – commonly known as the 'KPMG study' – had been published[55] the contestation over the numbers only intensified, illustrating the malleability of IA results. Some have emphasized that this study, although broadly confirming the Commission's own impact assessment, raised serious issues about the business impact of the proposed legislation on SMEs and downstream users.[56] Others have concluded that even though

> KPMG started with worst-case cost assumptions, none of the case studies identified problems as predicted by previous industry studies: no loss (withdrawal) of important chemicals because of registration costs, registration costs will largely be passed on or absorbed by the supply chain and product reformulations are not likely.[57]

54 E.g. on the account of a senior campaigner of environmental NGO Friends of the Earth who gave evidence before the Environmental Audit Committee of the House of Commons in the context of a report on the functioning of impact assessment.

55 The Working Group held its final meeting on 13 April 2005 where the findings were presented and discussed.

56 EurActiv, 28 April 2005.

57 Löfstedt (2007), 426.

The contested process *and* content were a fertile basis for further disagreements at all levels, including within the ranks of the Commission itself,[58] as the impact assessment went on to be used in the legislative process.

VI.1.4 The use of IA

Deliberative qualities crucial but lacking

Accounts of the use of the REACH IA vary greatly in their analysis of the facts as well as in their appreciation of those facts. On the most positive note the deliberative qualities of the IA process have been hailed:

> A case in point is the use of IA since 2003 in the REACH proposal to extend precautionary testing of chemicals to some 30,000 substances. IA has been extremely successful in enriching the public debate on the pros and cons of regulation and alternatives, such as risk-based approaches. Contrary to the fears of some environmental groups that IA weighs against protection, recent IAs project lower costs and job losses than anticipated, and hence reduce opposition to regulation.[59]

More negative assessments of the role IA played in this case strongly contest the idea that IA has helped building consensus in the REACH case, questioning the value of IA either as an informative or as a deliberative tool.

> [T]he RIAs conducted for REACH have been used as lobby instruments and are not unbiased measures of the actual costs and benefits, something noted by the European Parliament in its criticism of Arthur D. Little's RIA work for the German Industry Association (BDI).[60]

The environmental lobby not only fiercely criticized the process and content of the REACH IA(s) as discussed above, but also contest the use, accusing other stakeholders with opposite interests of disrespecting the procedural rules of deliberative democracy:

> Throughout the REACH debate, WWF and the other environmental NGOs have focussed on providing reasoned and reasonable input into the policy debate. We have been very disappointed that certain other parties to the debate, notably some

58 J. Pelkmans, 'Presentation on REACH', paper given at the Ceps conference on 'Impact Assessment in the EU, taking stock and looking forwards' on 23 January 2006 (Brussels, 2006).

59 Jacobs & Associates, 'The Better Regulator. Spring/Summer edition', (Washington DC, 2005), p. 2.

60 Wilkinson and Monkhouse et al. (2005), p. 29.

> representatives of industry, appear not to have taken this approach, and have been attempting to make political capital through scaremongering.[61]

WWF en EEB take the view that the impact assessments by ADL and Mercer had been discredited and that they can be blamed for still using the figures from those studies in presentations.

However, others are very critical of the 'non-committal' attitude of the environmental organizations and EEB in particular.[62] Their criticism – EEB should realise that these processes are characterised by give and take and opting out just because the results are not to its liking is not fair play – implicitly hinges on the deliberative qualities of the process too.

Aid to internal decision-making in the Commission

Staying on track with the REACH file was an extraordinarily painful process, certainly after the new Commission took office.[63] An interviewee conveyed the strong impression that the political level would never have supported an enormously costly proposal in the era of Better Regulation and the impact assessment actually helped show that the costs were not as high as many predicted.[64] In that sense, the flood of impact assessments did not really disturb the internal assessment and decision-making processes in the Commission. The many private IAs were rather seen as an opportunity to test and improve the solidity of the Commission IA by picking and choosing from the various analyses. In some cases the lobby IAs involuntarily supported the Commission IA. For instance, the fact that the costs stated in the Mercer study were so extraordinarily high made it only easier for DG Environment to argue that it was a political position paper rather than an objective assessment.[65] A final observation from an official involved is that changes to the proposal, including those proposed in the Room Paper, were always costed throughout the process, even if this did not lead to formal revision of the original impact assessment.[66]

Information overkill in the Parliament

> With 'REACH', however, the process has shown lamentable imperfections and mistakes. The upshot is that it has not helped MEPs.[67]

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61 WWF European Policy Office (Tony Long), 'Fair chemicals provision for EU is within Reach', Financial Times (2005).
62 Interview national official A.
63 Interview Commission official A.
64 *Ibid.*
65 *Ibid.*
66 *Ibid.*
67 MEP Monica Frassoni, McCarthy and Frassoni (2005).

Towards the end of 2003 the first reading by the European Parliament started. Initially the dossier was assigned to the Environment Committee who had been handling REACH since the days of the White Paper, in consultation with the Industry and Legal Affairs Committees. However, the Industry Committee challenged this allocation, claiming that they should lead the dossier instead. Amidst ongoing discussions about which committee should be awarded the lead on REACH, MEP Guido Sacconi, who had been appointed rapporteur by the Environment Committee, started working on his report.[68] Only after the elections the European Parliament managed to solve the conflict and debate the report. In the end, apart from the three lead committees, the Committee on the Environment, Public Health and Food Safety, the Committee on Industry and the Committee on Legal Affairs, as many as five other committees have been examining the REACH dossier.

During the debates on REACH in the Environment Committee on 29 March and 6 April 2004 some Committee members expressed their concern that the impact assessment only addressed potential impacts on business and did not include impacts and benefits to the environment and on social issues. Commissioner Dimas defended the Commission IA, stressing 'that a comprehensive impact assessment had already been carried out, which showed that benefits strongly outweighed costs, pointing to the necessity for awareness-raising to be brought to the fore'.[69] But later in the year more cracks appeared in the inter-institutional cooperation and the tone of the debate hardened.

Inter-institutional trouble

The handling of REACH proposal has been cited as an example of the lack of cooperation between the institutions on the Better Regulation agenda.[70] At a hearing which was really on Implementation, Impact and Consequences of Internal Market Legislation, organized by IMCO Committee on 15 September 2005, REACH was mentioned by Malcolm Harbour (EPP-ED) when he asked the Commission to pay more attention to the quality of impact assessment during the early phases of proposal preparation, quoting the REACH and the Services Directive dossiers as examples where better analysis would have made a difference. Having already stated earlier – at a parliamentary Committee

68 Rapporteur Guido Sacconi (ESP) was also the ENVI Committee's representative in the High Level Group on further impact assessment of REACH with Ms Oomen-Ruijten (EPP-ED) as substitute member. Nominations were confirmed at the Coordinators' meeting of the on 27 September 2004. See http://www.europarl.eu.int/comparl/envi/pdf/coordinators/coord20040927.pdf (last accessed 15 July 2007) under heading 'REACH'.

69 At the European Parliament Seminar on "The new REACH legislation", jointly organized by the Committee on the Environment, Public Health and Food Safety, the Committee on Industry, Research and Energy and the Committee on Internal Market and Consumer Protection on 19 January 2005.

70 By John Cridland, see House of Lords 9th report (2005), p. 7 of the Minutes of Evidence.

meeting in Strasbourg in early April 2005 – that the costs to industry of REACH were too high, Vice-President Verheugen answered that he would never have put that proposal in its original form on the table, admitting that he saw REACH as 'a clear example of legislation that is too complicated and too ambitious, too lacking in transparency'. According to Verheugen at that hearing, REACH is 'is the sort of legislation the Commission will never file again'.[71]

This kind of statement only fuelled existing rumours that the Commission had prepared an amended proposal in mid-September 2005 that would water down the proposal further than the compromise text from the UK Presidency of 6 September 2005, without any prior consultation with the Parliament. This 'Room Paper', which was presented at the Council Ad Hoc Working Group on 20 September 2005,[72] contained information on how far the Commission was prepared to go in accepting a watering down of safety data requirements. The paper was leaked to environmental lobby groups who claimed that it was a significant change of position and the result of a deal between Barroso, Verheugen and Dimas.[73] The manoeuvre allegedly also provoked the anger of former Environment Commissioner Margot Wallström, whose move from DG Environment to the post of Commissioner for Communications and Vice President when the Barroso Commission took office in autumn 2004 was an important factor in the watering down of the initial proposal.[74] The Room Paper incident also led an environmental think tank to conclude that 'there is little sign of the Commission applying its own Impact Assessment principles to its own major policy shift'.[75] Several Members of the European Parliament asked the Commission for clarification in this matter.[76] In its answers the Commission denied any plans to come up with a new proposal and said that the Room Paper (although that term was not used) was merely a response to a request from Council to the responsible Commissioners to indicate their positions with the latter actors considering it 'opportune to put the Commission negotiators in the position to participate in the debate'. In a twist that is a recurring tale in this thesis, lack of clarity on the status of supporting documents in the legislative process led to political contention over competences. In this case as well, the episode left a clear mark of distrust among some MEPs

71 European Parliament press release, The Internal Market: mission still unaccomplished, http://www.europarl.eu.int/news/expert/infopress_page/054-253-257-9-37-909-20050912IPR00218-14-09-2005-2005--false/default_nl.htm (last accessed 15 July 2007).

72 Council of the European Union (Ad-hoc Working Party on Chemicals), Working Document 301/05, DG C I, Brussels, 7 November 2005, http://ec.europa.eu/enterprise/reach/docs/reach/council_note_301_05.pdf (last accessed 18 July 2007).

73 Greenpeace, 'Toxic Lobby. How the chemicals industry is trying to kill REACH' (Brussels, 2006).

74 Löfstedt (2007), 427.

75 European Environment and Sustainable Development Advisory Councils (2006), p. 15.

76 See oral questions by MEP Jan Andersson on 28 September 2005 (H-0800/05), MEP Hélène Goudin on 29 September 2005 (H-0805/05) and MEP Jonas Sjöstedt on 17 October 2005 (H-0911/05).

and lobbyists and made the Commission vulnerable to accusations of having breached 'its institutional role of 'conciliator' between Council and Parliament, and taken a clear partisan position in the as yet unresolved discussions in the Council of Ministers'.[77]

Next to the normal legislative debates, the route of oral questions was used more than once by MEPs in order to get a complete picture of the impacts of REACH. MEP Chris Davies asked the Commission for its latest compliance costs estimates according to three different scenarios: a) no information available, b) information to meet current safety data requirements is available and c) information of a nature that the Commission believes most manufacturers will in practice already have acquired is available. On 28 April 2005 three MEPs put an oral question to the Commission, asking whether it considered the increase in costs to the chemical industry estimated by the KPMG study (between 6% and 20%) acceptable.[78] In his question to the Commission on REACH and international trade[79] MEP Schlyter asked whether the REACH IA had also considered 'what advantages and disadvantages this legislation may have for developing countries in general and ACP countries specifically?'

The engagement of the Parliament with stakeholders was by no means uncritical. An MEP of the Greens/European Free Alliance voiced the same accusation as the environmental lobby groups:

> Continuing to use disproven figures, Cefic and ACC went on to say that the cost of testing was estimated at €7 billion, although the estimate in the impact assessment from May 2002 said that the cost would be between 1.4 and 7 billion, with a best estimate of 3.6 billion.[80]

Also, Caroline Jackson (PPE-DE), then chair of the Environment Committee, suggested at a stakeholder seminar that if the industry wanted to come up with an alternative proposal for REACH it should be accompanied by an impact assessment.[81]

An ITRE-commissioned 'IA'

The Committee on Industry, Research and Energy of the European Parliament (ITRE) joined the list of actors producing their own IAs and issued a limited

77 Greenpeace, 'Toxic Lobby. How the chemicals industry is trying to kill REACH' (Brussels, 2006), p. 12.
78 Oral question by MEPs Ivo Belet, Werner Langen and Paul Rübig on behalf of the PPE-DE Group to the Commission, 28 April 2005 (O-0067/05).
79 Question no 59 by Carl Schlyter (H-0369/05).
80 Waxman report (2004).
81 The AllChemE Seminars, Where science meets society. The socio-economic importance of chemistry in Europe. http://www.allchemeseminars.org/downloads/04-01-28/Final%20Report%20%2028-01-04.pdf (last accessed 15 July 2007).

call for tender in July 2003. The result was a small study by Arthur D. Little entitled 'New Proposals for Chemicals Policy: Effects on the competitiveness of the Chemical industry'.[82] It contained a cost figure that was many times higher than that of the Commission, predicting a dramatic "2.9% loss in GDP and a 24.7% loss in production" over a 20 year period. The study was never labelled as 'impact assessment' and published on the Parliament's website as a 'study' in April 2004.[83] The study received heavy criticism from within the ranks of the ITRE Committee as well as from the Commission and other stakeholders. In the discussion that followed the presentation of the study by consultants from Arthur D. Little (ADL) several MEPs – and not only those belonging to the Greens/EFA – criticized the relevance, the methodology as well as the objectivity of the study. Interestingly, MEP Satu Maijastiina Hassi (Greens/EFA) disqualified the study as 'not objective' *because* it did not outline any potential benefits from REACH.[84] Another MEP Renato Brunetta (EPP) also seemed to tie legitimacy of IA to the use of cost-benefit analysis, asking – as part of a criticism of the methodology used in the study – why traditional cost-benefit analysis had not been used.[85] A briefing document by the Greens/EFA in the European Parliament in which the ITRE study was compared to the German Industry Association (BDI) study that was also carried out by ADL[86] set out in detail why the methodology and the objectivity were doubted. First of all, ADL was still under contract with the German Industry Association (BDI) in relation to the production of the third of a series of IA studies for them when the firm started the work for the ITRE Committee. Furthermore the methodology was alleged to be the same as the one used in the BDI study even though it had already been criticized by several economists. A comparison of the two also showed that some phrases were almost the same and that the – Commission proposal-friendly – Joint Research Centre (JRC) impact study had been quoted selectively.

A real impact in Council

> [I]mpact assessments have played a central role in informing the ongoing negotiations on the REACH proposal.[87]

82 Arthur D. Little, 'New Proposals for Chemicals Policy: Effects on the competitiveness of the Chemical industry', Study for the Directorate General for Research of the European Parliament, EP/IV/A/2003/07/03-2 (Brussels, 2004).

83 *Ibid.*

84 European Parliament, 'News Report', 31 August 2004. Emphasis AM.

85 *Ibid.*

86 Arthur D. Little, 'Economic Effects of the EU Substances Policy. Study for the German industry association BDI' (Brussels, 2002).

87 Better Regulation, Progress report from the Presidency 5 October 2005, p. 3.

REACH is frequently mentioned as one of the few examples of IA having had an impact on the negotiations in Council:

> The REACH Directive is the best example I would give […] of where you have an impact assessment that is beginning to make a difference.[…] The benefits to the UK and the European Union chemical industry will be significant *because of the improvements an impact assessment will make*.[88]

During the hearing organized by the European Union Committee of the House of Lords in preparation of their report on Ensuring Effective Regulation in the EU on 14 June 2005, Sir David Arculus, Chairman of the UK Better Regulation Task Force, was posed the question whether he could 'point to any single draft Directive where the Council of Ministers has apparently been influenced by an impact assessment?' He answered:

> Yes, the Chemicals Directive where the initial cost was reckoned to be something like 25 billion and that has been greatly reduced by the various impact assessments that have been involved.[89]

For the decision-making in Council, the Competitiveness Council was the lead Council formation[90] but the Environment Council was also involved. In its conclusions the European Council of 16-17 October 2003 explicitly called for an impact assessment from the Commission, tying it to a particular view on competitiveness:

> The Council and the Commission must address the needs of specific industrial sectors, especially the manufacturing sector, in order for them to enhance their competitiveness, notably in view of their essential contribution to economic growth. EU legislation should not be a handicap to EU competitiveness compared to that of other major economic areas. To this end the Commission is invited to take into account the consequences of proposed EU legislation on enterprises through providing a comprehensive impact assessment. The forthcoming proposal on chemicals, which will be examined by the Competitiveness Council in coordination with other Council configurations, will be the first case for implementing this approach, taking in particular into account its effects on SMEs.[91]

The distinct impression of a participant in the REACH Working Parties was that the impact assessments had a catalysing role in the discussions, with the 'institutional IAs' carrying more weight than the 'private IAs'.[92] A Council ad hoc working group consisting of experts and Member States government

88 Quote from Mr Hutton, House of Lords 9th report (2005), 26. Emphasis AM.
89 Pelkmans (2005).
90 Decided by the European Council on 16-17 October 2003.
91 Council conclusions (2003), p. 6.
92 Interview national official A.

representatives from both Environment and Industry Departments was established especially for REACH in late 2003 and met in Brussels every two or three weeks. These meetings were the main forum for the preparatory negotiations on the REACH proposal.[93] The workshop on REACH IA organized by the Dutch Presidency in October 2004 (see above) can be seen as an extension of this working group. Within the Dutch administration the workshop is reportedly looked upon in a positive way, as some real conclusions were drawn which came in handy during the course of the further negotiation process. The workshop was perceived as very useful, particularly because its conclusions could be fed straight into the negotiation process in Council.[94]

One year later the Luxembourg Presidency followed suit and organized a REACH workshop on 10 and 11 May 2005. Strangely enough the focus of the workshop seemed to be on aspects which normally occur very early on in the IA process (data and options) whereas the Dutch workshop held in the previous year had focussed on issues belonging to the final stage (cost-saving measures):

> This workshop focused on the results of different impact studies. It also held an in-depth discussion of alternative approaches adopted by the Member States, in particular as regards the 'one substance, one registration' (OSOR) proposal, a proposal on substances present in products and an alternative approach in the area of registration and evaluation of substances produced in small quantities (1 to 10 tonnes).

REACH is again an unusual case in that the Council has officially concluded its review of all the IAs under the Luxembourg Presidency. At the orientation debate on REACH in the Competitiveness Council on 6 June 2005 '[t]he discussion also focused on the conclusions to be drawn from the additional work on impact analysis carried within the framework of the framework agreement between the Commission and industry'. A press release from the Luxembourg Presidency reports that the 'Council is committed to taking into account all the results drawn from the impact studies once the political decision is made'. According to chairman Jeannot Krecké, the general feeling in the Competitiveness Council was that 'the purpose of impact studies is not to produce a perfect state of information on REACH, but rather to provide as much information as possible.' The chairman continued:

> I think that with 50 impact studies, the time has come for the Council to conclude, to make the necessary political decisions with a view to increasing the feasibility and viability of REACH. This is the opinion of the Presidency as well as of the majority of the Ministers. We have rarely, probably never, carried out so many

93 Ms Margo Monaghan, Irish delegate in the special *ad hoc* Council working group on REACH at a meeting of the Committee on Enterprise and Small Business of the Irish Oireachtas on Scrutiny of EU proposals on Thursday, 21 April 2005.

94 Interview national official A.

> impact studies. Both consumers and enterprises will find themselves at ease in the REACH regulation. If we wait for perfect information, we will be in the situation of someone who doesn't want to buy a PC unless the technology is flawless and will not be improved anymore. He will never end up buying it.[95]

These words can be interpreted as 'enough assessed, let's do business' and according to one observer that is exactly what happened. Once the negotiations on REACH had really taken off (under the UK Presidency) things moved quickly and the IAs no longer played a role.[96] The Council reached unanimous political agreement on on 13 December 2005 and adopted the Common Position formally on 27 June 2006.[97] Half a year later, on 18 December 2006, the REACH regulation was adopted.[98]

VI.1.5 Synthesis

From the most positive perspective the use of IA in REACH was an example of a successful learning process: because of IA decision-makers allegedly managed to bring down the cost of REACH by 8 billion euros. On a more negative note REACH is the prime example of the inequality in terms of resources available to produce additional studies to industrial lobby groups on the one hand and environmental NGOs on the other and of how the new IA procedure is not capable of taking this into account.[99] Although many IA stakeholders, as well as the Commission, have claimed that competitiveness is much wider than the narrow category of 'expenses for European businesses', the REACH case indicates that the concept tends to prioritise short- term and cost-based arguments to some extent.

There is an argument to be made that the type of assessment used in the 'original IA' namely a cost-effectiveness test rather than a form of cost-benefit analysis, is appropriate for the stage the policy development was in at the time of the 'original IA'. The problem in this case was that a lot of the IA work kept

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95 Luxembourg Presidency, Press Release, Jeannot Krecké on REACH: "I think that with 50 impact studies, the time has come for the Council to conclude", 06 June 2005, http://www.eu2005.lu/en/actualites/communiques/2005/06/06reach/index.html (last accessed 15 May 2007).

96 Informal communication Council official.

97 OJ C 276E, 14 November 2006.

98 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30 December 2006, pp. 1–849.

99 Schörling (2004), p. 136.

floating in between cost-effectiveness testing and CBA, forever giving stakeholders a reason to lament the quality of the assessment.

At a European Parliament hearing for Commissioners-designate Günter Verheugen was asked specifically about the REACH impact assessment, including the question 'should the REACH impact assessment be considered a model for EU legislation?' He answered:

> Because of its complexity and the significance of the likely impacts, the preparation of REACH was very thorough in terms of analyses carried out and stakeholder consultation.(…) The Commission has followed its existing policy on Better Regulation by undertaking an extended impact assessment on REACH and is now engaged in further work, involving all stakeholders, to explore certain implementation aspects in more detail. (…) However, the continuation of impact assessment work following the adoption of the Commission's proposal reflects the particular complexity of this case.(…) The Commission will have to carefully monitor the competitiveness issue throughout the whole legislative process.[100]

Between the lines, his answer seems to be a 'no'. Rather interestingly the question was also posed whether REACH was unique in requiring a comprehensive impact assessment and cost benefit analysis. Should we, like Verheugen who answered with a patient explanation of the introduction of new impact assessment requirements in 2003, take this to imply that some MEPs were not previously aware of the existence of the new impact assessment system?

In any case, it seems warranted to conclude with Pelkmans that '[f]or REACH much of what it takes to provide MEPs with the information for a careful political decision to legislate has been breached'.[101] But is it a case of paralysis by analysis or rather a case of pure power politics (facilitated by IA)? Although there are some traces of the former phenomenon (the Council deciding to move forward with negotiations without any IA and the Parliament being unable to process all the contradictory information) a stark image of the latter emerges from this case study.

The use if impact assessment in the REACH case also raises questions about whether objectivity can be attained and about the feasibility of the Commission's resolve to have their impact assessment as *the* impact assessment throughout the legislative process. Answering a question from an interviewer sceptical about the use of IA in environmental policy, Stavros Dimas, the Commissioner for the Environment, commented:

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100 Günter Verheugen (Commissioner for Enterprise and Industry), European Parliament Hearings, Answers to Questionnaire for Commissioner Designate, Part B – Specific questions. See http://www.europarl.eu.int/meetdocs/2004_2009/documents/dv/539/539145/539145en.pdf (last accessed 15 July 2007).

101 Pelkmans (2005).

> Impact assessments are of course a useful tool. Political decisions are something different. You take a political decision and you base your judgment and your ultimate decision on various elements that you have at your disposal. Impact assessments are an important element, but sometimes you have other political targets. Nevertheless, impact assessments are a valuable asset and REACH is one example. You mentioned that there were fifty impact assessments. *The Commission of course relies on its initial extended impact assessment* which still stands – even after the one carried out under the memorandum of understanding – more or less confirming the findings of this impact assessment.[102]

From the REACH saga the image of the IA procedure as a market place emerges here and there. The Commission should not expect to have the 'monopoly' in producing an IA; if the 'IA product' falls below 'market standards' demand for IAs rises and the Commission's monopoly is forced open. Yet at the same time, all players seem to assume that IA is a public good: whether it is the corporate lobbies who feel they should not have to pay for further impact assessment, the environmental lobbies who battle for access to data or the Council working party that gives more weight to 'institutional IAs' than 'private IAs'.

VI.2 CAFE: THE LEGITIMACY OF SECOND BEST

Whereas many – also within the Commission – would probably agree that the REACH IA was not a case of best practice, the IA for the Air Quality Thematic Strategy (CAFE)[103] – one of the most comprehensive IAs ever produced by the Commission – is often explicitly presented as an example of Better Regulation.[104] However, below the surface there are a few significant qualifications to make. As it turns out, a 'good' IA is no guarantee for a smooth decision-making process.

VI.2.1 Background in brief

As part of the Sixth Environment Action Programme (6th EAP), which sets objectives for action and several thematic strategies to address important aspects of the environment, the regulatory framework on air quality was

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102 EurActiv, 19 December 2005, Interview with Environment Commissioner Stavros Dimas, http://www.euractiv.com/Article?tcmuri=tcm:29-139272-16&type=Interview (last accessed 15 July 2007).

103 European Commission, Impact Assessment of the Communication on Thematic Strategy on Air Pollution and the Directive on "Ambient Air Quality and Cleaner Air for Europe", Commission staff working paper, SEC (2005) 1133.

104 Löfstedt (2007), 435. "A major effort in 'Better Regulation' in the environment field will be reflected in the seven Thematic Strategies".

revised, explicitly in line with the Commission's strategic objectives for 2005-2009 calling for Better Regulation. The commitment to Better Regulation was interpreted here as an imperative 'to modernise and simplify the current air quality legislation – and to reduce its volume – in order to improve the competitiveness of the European economy'.[105] The combined impact assessment[106] of the Communication on Thematic Strategy on Air Pollution[107] and the Directive on 'Ambient Air Quality and Cleaner Air for Europe'[108] has come to be known as the 'CAFE impact assessment'.

VI.2.2 The IA process

The process of assessing the impacts of CAFE was very much intertwined with the preparation of the proposal and as with all Thematic Strategies on the Environment, the resulting impact assessment was also presented as integral part of the proposal. The IA was prepared in a Steering Group and several smaller working groups, allowing for involvement from various stakeholders (industry federations, environmental NGOs, research institutes and representatives from Member States, throughout the process. Not only the data but also the wider terms of reference (models, scenarios and assumptions) were discussed in this Steering Group and the working groups, leading most observers to qualify the process as inclusive,[109] although there were still some 'private IAs'.[110]

VI.2.3 The IA content

The IA claims to *describe* 'the options considered in developing the Thematic Strategy on Air Pollution' (the Strategy) and to *justify* 'the choices presented in the Strategy and in the Commission's proposal to revise the air quality framework directive, the first three daughter directives and the Council decision on the exchange of air quality information' (the Air Quality Proposal).[111] The IA report does a lot and it even highlights trade-offs, still a relatively rare achievement in Commission IAs, but 'justification' is exactly where the IA can be said to fall short.

105 SEC(2005) 1133, p. 135.
106 *Ibid.*
107 COM(2005) 446 final.
108 COM(2005) 447 final. The proposed directive incorporates the First, Second and Third Daughter Directives on Clean Air, as well as the Exchange of Information Decision.
109 European Environment and Sustainable Development Advisory Councils (2006), p. 12. The Evaluation Partnership (TEP) (2007), p. 76.
110 Interview Commission official A.
111 COM(2005) 447 final.

The IA is a very lengthy document that leaves some readers with the distinct impression that some elements that could not be fitted into the actual strategy document have been included in the IA instead.[112] At 170 pages the CAFE IA is bound to be a much more thorough assessment than the REACH IA with 33. To start with, one clear element of good practice is that the IA lists all the service contracts that have been awarded to consultancies under the CAFE programme.[113]

But there are many more elements of uncontested good practice in the CAFE IA. The selection of the three options to be subjected to in-depth analysis is sophisticated. Various options between the baseline and the Maximum Technically Feasible Reduction scenario (a scenario whereby all possible emissions abatement measures are deployed irrespective of cost) were assessed to establish interim environment objectives. In consultation with the Working Group on Target Setting and Policy Assessment, three different levels of ambition were considered in four areas. Subsequently, the three scenarios between the baseline and the Maximum Technically Feasible Reduction scenario were subjected to a full cost-benefit analysis, complemented by analysis of impacts on competitiveness and employment.[114] The IA also takes care to include a sensitivity analysis and to list uncertainties in the model used and in the cost-benefit analysis.[115] All three scenarios were reported to pass the cost-benefit test the IA also contended that the wider economic and social impacts of all options were demonstrated to be compatible with the EU's Lisbon and sustainable development strategies.[116]

The IA itself is widely regarded as an example of best practice. One important reason why so few actors questioned the correctness of the IA results[117] is that the IA made use of well-developed models. This extensive modelling had been developed in the course of many years of experience with impact assessment and structured dialogue between stakeholders, experts and national officials in this area.[118] Even an observer who felt that DG Environment wrote up the IA in a biased way immediately added that 'it did not matter, since the numbers were there'.[119] So far the CAFE IA seems a perfect example of how IA can mitigate political disagreement by showing the numbers. However, opinions are more divided as to whether the *use* of the CAFE IA in the decision-making process also represents good practice.

112 Interview national official B.
113 SEC(2005) 1133, p. 9.
114 *Ibid.*, p. 12.
115 *Ibid.*, pp. 166-170.
116 *Ibid.*, p. 128.
117 The European Parliament rapporteur, Dorette Corbey also indicated in a phone interview that she found the data in the IA report convincing.
118 Wilkinson and Monkhouse et al. (2005), p. 16.
119 Informal communication EU official.

VI.2.4 The use of IA

The dilemma that came to light through the IA was that although in all scenarios considered the benefits were greater than the costs, the cost curve rose sharply from a certain ambition level onwards with the benefits only increasing marginally. The chosen policy option was expected to deliver € 42 billion in benefits per year at a cost of around € 7.1 billion per year. The benefits were said to include the prevention of 62,000 premature deaths, whereas an earlier more ambitious proposal would have prevented 74,000 premature deaths with the benefits still outweighing the costs. This led certain critics to ask whether this is a legitimate use of cost-benefits figures.[120]

> [T]he Commission opted for an approach that reaped only the relatively low hanging fruits, although the Impact Assessment could have justified a more ambitious approach, as preferred by a majority of experts in the Working Group.[121]

Aid to internal decision-making in the Commission

The launch of the proposal for the Thematic Strategy took place amongst the 'Lisbonisation' of the Better Regulation strategy, symbolically – albeit surely unintentionally so – even on the same day as the Edinburgh conference organized by the UK Presidency to raise support for Better Regulation among business stakeholders. In this climate, the package of seven environmental strategies, inherited from the Prodi Commission, was not received warmly by the new Commission. In particular DG Enterprise, objected to the package claiming that it was not in line with Better Regulation principles. In the end Commissioner Dimas managed to negotiate versions of the Strategies that were 'Better Regulation proof' in the eyes of DG Enterprise.[122] In the specific case of CAFE there was a prime role for the IA in the internal negotiations.

During a debate on CAFE in the Competitiveness Council Group of Commissioners in early June 2005 Vice-President Verheugen asked Commissioner Dimas for Environment to come along and present the IA. In the eyes of DG Environment the IA supported a more ambitious option. But Verheugen mainly focussed on the cost-aspect brought to light by the IA. Although this process has been applauded as an instance of an IA actually aiding political decision-making in the Commission it also revealed how difficult it is to have a political discussion that does justice to the IA. Despite evidence that the IA has been discussed by the Commissioners, it is widely assumed that the final proposal only contained the less ambitious option because that was the one which had political support.

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120 European Environment and Sustainable Development Advisory Councils (2006), p. 12.
121 Wilkinson and Monkhouse et al. (2005), p. 16.
122 According to Löfstedt a special hearing was held for this purpose. Löfstedt (2007), 435.

The IA report does include a section explaining how the results of the IA led to the choices made in the Commission proposal. One paragraph merits full citation:

> Scenario C has the advantage of delivering high environmental and health benefits. However, at the same time the annual costs of Scenario C are about €4 billion higher than in Scenario B. A cautious marginal analysis approach, taking into account the uncertainties, shows that the optimum level of ambition for PM health benefits is between B and C. Regarding the other targets for ecosystems and ozone for which a monetary valuation is not fully available, additional ecosystem benefits between Scenarios A and B are relatively small compared with the increase in costs. Therefore, it seems justified to select a final scenario which represents a combination of Scenarios A and B, i.e. a level of ambition for human health protection from PM close to Scenario B with a level of protection for ecosystems based on Scenario A. This delivers the lowest levels of air pollution that can be justified in terms of benefits and costs whilst attempting to prevent undue risks for the population.[123]

Although the reasoning seems a bit contrived, the Commission clearly stated here that its decision criterion was not 'maximisation of net benefits' but rather 'cost-effectiveness within a simple cost-benefit test'.

Parliament: contesting second best

Commissioner for the Environment, Stavros Dimas finished his defence of the Thematic Strategies on Air Pollution in front of the European Parliament on Monday 4 July 2005 proposal with the following statement:

> The air strategy has been thoroughly prepared; it is based on sound science and economics. It has gone through extensive stakeholder consultations and full impact assessment, as well as cost benefit assessment.

However, many MEPs have asked what use has been made of all this thorough assessment.

Although the CAFE dossier does not fall within the ambit of the codecision procedure and all the European Parliament and the Council can do is issue an opinion, the Strategy was discussed at length. In the ENVI Committee an exchange of views was held on the Commission proposals. Holger Krahmer (ALDE, Germany) was appointed rapporteur for the proposal aimed at revising existing Community legislation on ambient air quality and Dorette Corbey (PSE, the Netherlands) was made rapporteur for the more general Thematic Strategy. The exchange of views focussed on the impact assessment supporting the specific options set out in the legislative proposal and the various scenarios

123 SEC(2005) 1133, p. 129.

examined in the thematic strategy.[124] A central question in the debate in the Committee was 'does the Strategy flow from the Impact Assessment?', with a special section in the externally commissioned briefing note even bearing this exact title. The verdict of the briefing note, by consultants of IEEP and IVM, research institutes specialised in environmental policy is the following:

> The rationale behind this [choice] is presented logically, but the reason behind the choice of the exact emissions reduction objectives is not clear. Instead, it is argued that this choice 'delivers the lowest levels of air pollution that can be justified in terms of benefits and costs whilst attempting to prevent undue risk for the population'. This choice is not a point where costs outweigh benefits, as the IA shows that more stringent measures would still deliver benefits that outweigh costs. The justification must, therefore, arise from political considerations rather than directly out of the IA itself.[125]

Rapporteur Corbey asked the Commission for clarification on the reason behind the choice for ambition level a+ but says that she did not get an explicit answer.[126] This left her to assume it was a political decision, possibly in combination with reasons of cost-effectiveness. She contends however that an ambition level between b and c would have been the logical choice flowing from the IA that would have represented a good balance between the costs and the benefits. She wrote in her report:

> Following consultations on the Impact Assessment (IEEP) and after hearing recommendations from health experts, your rapporteur takes the view that the level of ambition opted for should be higher.[127]

The briefing note contains some further concerns, shared by the rapporteur:

> The concern is that the Thematic Strategy itself contains little in the way of proposals for concrete action to deliver its objectives. Indeed the only concrete proposal accompanying the Communication is a draft Directive that reduces obligations on Member States. The lack of clarity on why a particular set of objectives has been identified in the Thematic Strategy is to be regretted. It should be noted that implementation of these (which some organizations consider to be too weak) will only be delivered through further proposals (such as a revision to the national emission ceilings Directive), which would again open up debate on these issues

124 ENVI news, Newsletter from the European Parliament Environment, Public Health and Food Safety Committee, 02/2006, http://www.europarl.eu.int/comparl/envi/pdf/envinews/2006/200602.pdf (last accessed 15 July 2007).
125 EP Policy Brief CAFE (2006), p. 3.
126 Interview with MEP Dorette Corbey.
127 EP report Corbey CAFE (2006).

including different vested interests, but no longer in the integrated context of CAFE.[128]

Corbey also felt that a disadvantage of the extensive use of IA in this case is that the Commission was thinking in terms of the three scenarios exclusively whereas it might have been more fruitful to choose 'option b' for some areas and 'option c' for others.[129] There is a tentative link here with Baldwin's hypothesis that IA is not capable of fostering 'smart regulation' as it encourages rigidity (see II.3.2).[130]

Council: benign indifference

The UK Presidency reported that there has been discussion on the CAFE IA in the Council working party on 24 October 2005, where the Commission held a presentation on the content of the IA. The outcome of this discussion was recorded in a report to COREPER,[131] which states that delegations were invited to provide written comments using key steps of good quality impact assessment as provided by the Presidency and in accordance with the Commission's guidelines of 15 June 2005. The Working party delegates then had an opportunity to ask questions or express criticism. Observers report that this opportunity was only used to a limited degree, certainly compared to the vastness of the IA, possibly because the proposal contained no controversial or new elements.[132]

The report gives the impression however that the impact assessment was discussed rather thoroughly, with delegates especially praising the IA process as open, transparent and almost exemplary. For each key step of IA some delegations expressed concerns. On the problem definition there were suggestions that the evolution of the problem could be different when taking into account the expected positive effects on air quality of Community and climate change measures, as well as criticisms on the lack of presentation of costs for different sectors and industries for each Member State individually. Furthermore:

128 EP Policy Brief CAFE (2006), pp. 12-13.
129 Interview with MEP Dorette Corbey.
130 R. Baldwin, 'Is Better Regulation Smarter Regulation?' [2005] *Public Law*, 485 *et seq.*
131 Document number 14657/05, Preparation of the Council (Environment) Meeting on 2 December 2005 Thematic Strategy on Air Pollution Proposal for a Directive of the European Parliament and of the Council on Ambient Air Quality and Cleaner Air for Europe policy debate. Access to document granted by Council secretariat.
132 Assessment of air quality policy is 'work in progress' that has been ongoing for 25 years, developed by among others the various task forces en experts groups of the UNECE Convention on Long Range Transboundary Air Pollution (CLTRAP). Besides, the RAINS model had already been used for the Gothenburg Protocol and the NEC Directive.

> Some delegations had the impression that the *definition* of the *objectives* was premature without the evaluation of lessons learned in the implementation and effectiveness of existing legislation, namely the National Emissions Ceilings Directive. Some delegations suggested that the comparison between the proposed scenarios and those developed at national level would allow to assess the feasibility of the objectives presented by the Commission. Regarding the *range of options*, some felt that a higher level of ambition would be desirable and possible without unreasonable abatement costs and that environmental objectives can be achieved with justified measures from a cost-benefit perspective.
>
> As far as the extended *analysis of impact* by the Commission is concerned, several delegations drew attention to a certain number of uncertainties, like the consistency of the energy forecasts with the obligations under the Kyoto Protocol and, most important, the uncertainty on particulate matter.
> As far as comparison of *policy options* is concerned, some delegations pointed out that a uniform limit value for fine particulate matter may not be, according to the Impact Assessment, neither technically nor economically achievable for all Member States, and will involve uneven costs. Others have referred that policy options should result from scenarios validated at all levels, in particular at Member States level, specially regarding costs.
> Some delegations felt that given the need of exploring further the objectives of the Thematic Strategy, aspects of *evaluation* could not be considered at this stage.[133]

In the report to the Council, the discussion on the Commission impact assessment does not return,[134] but a request for future impact assessments is included in the conclusions of the Environment Council of 6 March 2006 in which the Council considers 'the ambition levels presented as an appropriate basis for further consideration, provided that all future measures are subjected to thorough impact assessment and updated projections are taken into account'.

One reason for the relative meek reactions to the Commission IA in Council could be of a strategic nature. There is often little reason for Member States to be very specific in their opinion of the proposal in the pre-negotiation phase, the only one in which the IA has a role. Just like in the European Parliament, the one important question – on the reasons why the Commission had chosen the particular level of ambition recommended in the IA – remained unanswered. Perhaps the Council did not press for an answer at any level because there was a strong sense that the exact level of ambition did not matter that much. After the adoption of the Strategy the Commission will come forward with legislative proposals and that is when the Council will really have a decisive say in the matter.

Although the modelling used and the resulting data were not contested, there was a clear sense among Member States that the IA was specifically

133 Document number 14657/05, 3-4.
134 Document number 14657/1/05. Access granted by Council secretariat.

drafted to fit the mould of the proposal. From the Commission's perspective this is justified: IA is meant to aid concrete policy-making; from the perspective of the Council exploration of more policy options, including concrete plans to reduce emissions at the Community level, is more useful as the primary function of IA is providing maximum information that can be used in negotiations.

The Council as such never considered engaging in additional IA work,[135] but there were some limited attempts by Member States at producing national IAs for use in the decision-making in Council. The Dutch administration commissioned a study on fine dust and the implications of the Commission proposal for the Netherlands, which was translated into English and distributed among all Member States.

VI.2.5 Synthesis

In the literature on lobbying the CAFE case has been mentioned as an example of 'compromised success', meaning that both environmentalists and industry achieved some of their goals but not all. The result meant tougher standards on emissions but the regulatory framework is not as far-reaching as initially proposed.[136]

In the case of CAFE process and content went relatively uncontested, but the use of the IA in the decision-making process spurred passionate reactions from all sides, revealing disagreement on the appropriate decision criterion. Whereas one observer remarked that 'it was an epiphany seeing an IA used as it should be'[137] to others the good quality of the IA was simply not reflected in the proposal.[138] The disagreement essentially hinges on the difference between maximisation of net-benefits and cost-effectiveness. Given the reactions of various stakeholders, the use of the CAFE IA illustrates though how easily IA gets confused with cost-benefit analysis (already at Commission level in this case) and how hard it is to hold on to the idea of using impact assessment as an information tool rather than as a decision tool. Surprisingly perhaps, the Parliament showed itself to be a proponent of full cost-benefit analysis, as also hinted in its own IA on the pre-packaging directive (see VII.1):

> An essential requirement of Better Regulation is that the benefits of new regulation outweigh the costs of implementing it.[139]

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135 Interview national official B.

136 C. Mahoney, 'Lobbying Success in the United States and the European Union' (2007) 27 *Journal of Public Policy*, 35-56.

137 Informal communication EU official.

138 Remark by a participant at the European Commission conference on Impact Assessment, 20 March 2006, Brussels.

139 EP Impact Assessment Study Pre-packaging (2005), p. 12.

The European Parliament claimed to have reason on its side, insisting that the IA pointed to the 'rational choice' and the Commission failed to bear the consequences from the IA.[140] Proponents say that the IA fully justifies the Commission's choice, because the marginal benefits of the higher ambition level were low and therefore could not justify the costs to business. The Commission certainly lived up to its own motto that IA should be 'an aid to decision-making, not a substitute for political judgment',[141] although the case study also illustrates that the meaning of that phrase is unclear. The case illustrates that after the decision has been made, partly based on 'political judgment' it becomes a lot harder to legitimate when an IA has been made but the relation between the IA and the decision is not transparent. It is striking that actors seem to share the presumption that the IA should dictate a certain option. Laying down several options with their respective trade-offs and then leaving it to the political level to make a political choice is the ultimate goal. This case could have been a triumph for the highlighting trade-offs model, except that it turned out to be hard to communicate the events in that light. Even if the Commission IA did contain text explaining how the IA results had been used and what the politically preferred set of trade-offs was, not many actors in the legislative process have picked up on this. There were also deliberate elements, in the sense that actors were forced to articulate their preferences and rephrase them in terms of the IA framework.

VI.3 THE CASES COMPARED

The usage of IA differs enormously from the one case to the other. To begin with, in the REACH case there were many scattered IAs on the subject, whereas in the case of CAFE there was one lengthy comprehensive assessment the quality of which was not challenged. In REACH the process and the content were so contested that stakeholders did not even get to the point of arguing about the use, as their was no single, omni-authoritative IA to be used. In CAFE it was rather the other way around: relatively uncontested process and content paved the way for contestation on the use. One shared point of criticism that emerged from the discussions based on the respective IAs is the relative inflexibility of decision-making through IA as the money and time invested in assessment paradoxically forces policy-makers to prioritise and define policy options early on, rather than remaining open to 'smart regulation'.[142] Both cases show that the interpretation of IA documents and their status in the policy process is never straightforward. They also illustrate that disagreement on substance is inevitably connected to disagreement on procedure, albeit in different ways in the two cases.

140 Interview with MEP Dorette Corbey.
141 COM(2002) 276 final, p. 3.
142 Baldwin (2005).

VII Case-studies II: making the case for EU action: market liberalisation and JLS

This chapter presents two cases which differ in many respects, following the template of process, content and use of IA as set out in the beginning of the previous chapter (see chapter VI). The first case – the new rules on Nominal Quantities for Pre-Packed Products – represent a classical case of market regulation: to what extent can determination of pack sizes be left to the market without consumers' interests being violated? And to what extent should the EU aim for harmonisation of the national rules in this area? The harmonisation question is also pivotal to the second case, the Directive on Data Retention. However this case falls outside the traditional realm of EU lawmaking and ventures into the area of criminal law, traditionally left to Member States.

VII.1 PACK SIZES: ONE SIZE DOES NOT FIT ALL

> [T]he proposed directive on pre-packaging seems to be a very technical dossier. However, in reality, it is part of the major policy initiative strongly supported by our institutions on better regulation and simplification.[1]

VII.1.1 Background in brief

The basic issue at stake in this legislative dossier is whether it is necessary to regulate the sizes of the packs in which a lot of basic foods are pre-packaged before they are sold. The legal framework for sizes of pre-packaged products consisted of a patchwork of national and European rules dating from the 1970s leading to both mandatory and optional sizes. Where European legislation did not fix sizes, Member States had the possibility to fix pack sizes for these products at the national level. However the Court of Justice confirmed in the Cidrerie Ruwet case[2] that these national, mandatory pack sizes formed an obstacle to the internal market and ruled that the *Cassis de Dijon* case law on

1 Commissioner Verheugen at the plenary debate in the European Parliament on 1 February 2006.

2 *Cidrerie Ruwet SA v. Cidre Stassen SA and HP Bulmer Ltd*, Case No. C-3/99 [2000] ECR I-8749.

'mutual recognition' also applied to national pack sizes.[3] As a matter of compliance with this case law but also as part of the SLIM programme (see II.1) and later on explicitly as a Better Regulation initiative, the Commission put forward a proposal to abolish the legislation fixing nominal quantities in which various products can be sold,[4] widely considered to be out of date as a regulatory framework. The three co-legislators – the European Parliament, the Council and the Commission – agree that, as a matter of principle, liberalisation of pack sizes should be the starting point, since consumer protection can be sufficiently pursued through unit pricing, unfair commercial practices legislation and labelling.[5] However, as the legislative process progressed, disagreement arose between the Commission and the Council on the one hand and the Parliament on the other as to which sectors needed an exception to the rule of 'free pack sizes'. A fierce battle unfolded, with a central role for IA and stirred up by what can be seen as a French crusade against the deregulatory side of Better Regulation.[6]

3 Paragraph 2 of the summary of the judgment: 'Article 30 of the EC Treaty (now, after amendment, Article 28 EC) must be construed as precluding a Member State from prohibiting the marketing of a prepackage having a nominal volume not included in the Community range provided for in Directive 75/106 on the approximation of the laws of the Member States relating to the making-up by volume of certain prepackaged liquids, amended by Directives 79/1005, 85/10, 88/316 and 89/676, which is lawfully manufactured and marketed in another Member State, unless such a prohibition is designed to meet an overriding requirement relating to consumer protection, applies without distinction to national and imported products alike, is necessary in order to meet the requirement in question and is proportionate to the objective pursued, and that objective cannot be achieved by measures which are less restrictive of intra-Community trade. In order to determine whether there is in fact a risk that consumers will be misled by excessively close nominal volumes of the same liquid, a national court must have regard to all relevant factors, taking as its reference point the average consumer, reasonably well informed and reasonably observant and circumspect.'

4 The proposed directive would repeal Directives 75/106 and 80/232 and extend the scope of Directive 76/211.

5 The final IA report by the European Commission (SEC(2004) 1298.) mentions the following directives as the main instruments of consumer protection: Directive 2000/13 on labelling and presentation of foodstuffs (Article 2), Directive 84/450/EEC on misleading advertising (amended by Directive 97/55/EC to include provisions on comparative advertising), will be amended by COM(2003)356 final, of 18 June 2003: Proposal for a Directive of the EP and of the Council concerning unfair business-to-consumer commercial practices in the Internal Market, Directive 98/6/EC on consumer protection in the indication of the prices of products offered to consumers (prices per liter/kilogram): unit prices, which are mandatory for all products in supermarkets.

6 Although the British emotions could also run high at times, most notable when the media reported that the British loaf was in danger, see http://news.bbc.co.uk/1/hi/uk_politics/6644361.stm (last accessed 18 July 2007).

VII.1.2 The IA process

The IA that the Commission produced is widely regarded as an example of good practice, especially when the fact that it was among the earlier ones is taken into account. The final IA report, published on 25 October 2004, is a rather short document (17 pages) and represents the final output of a lengthy process featuring a survey, a consultation[7] and a draft impact assessment.[8]

The Commission services of DG Enterprise compiled a working document entitled 'Pack Sizes in the EU' in September 2002 which was the basis for the consultation on the basis of an expert study on innovation in pre-packaging which it commissioned.[9] This first study revealed conflicting visions among industry representatives. Some called freedom of pack sizes an innovative part of their products whereas others were very attached to fixed sizes.[10] A public, online consultation was held in 11 languages as well as a survey through the portal 'Your Voice in Europe'. On the basis of these results and the framework in the working document the services drew up the first general IA, which was put on the web and used for a second public consultation. The results of a Eurobarometer poll were also fed into the analysis.

There was close cooperation between DG Enterprise as the responsible DG and DG Environment and DG Health and Consumer Policy, which were both interested because of the subject matter of this liberalisation initiative.[11] DG Health and Consumer Policy indicated that it did not think the proposal would have important impacts on consumers, since consumers were already protected through various EU regulations and directives. Still, in 2004 the responsible Commission officials consulted the European Consumer Consultative Group (ECCG), consisting of national and regional consumer organizations in the 25 Member States. The final IA report stated that these organizations, as well as consumer organizations at the European level, were asked for their views on the basis of the documents on the general impact assessment and the impacts on the sectors asking for exemptions. Eight organizations, from six different Member States, responded with all but one indicating to be in favour of free sizes in general,[12] a result which supported DG Health and Consumer Policy's stance. Next to the Public consultation in November 2002 until January 2003 on the Working document of September 2002, the sectors requesting fixed sizes have been separately heard by the Commission services in June/July 2003. This special consultation together with the separate consultation of consumer

7 The consultation was held between 8 November 2002 and 31 January 2003 and the services reported the result in a document dated 28 May 2003.
8 EC BIA pre-packaging (2003).
9 EC Working Paper 'Pack Sizes in the EU' (2002).
10 Interview Commission official C.
11 *Ibid.*
12 SEC(2004) 1298.

organizations in 2004 led to a separate report entitled 'Pack sizes in the EU: Report on the extended impact assessment of sectors asking for fixed sizes'.[13]

An interview revealed that the development of the proposal proceeded parallel to the IA process. If a consulted sector expressed its preference for free sizes, the IA generally went along with that. If a sector insisted on fixed sizes, the necessary range of those was a topic for assessment. This is how the Commission services arrived at a strand of most sold fixed sizes for the wine sector (between ten centiliters and one and a half liters). In the perception of those responsible for the IA within the Commission services the IA process influenced the stakeholders. Through the process of having to specify their objections to a liberalisation of pack sizes many industry representatives gradually withdrew their initial opposition.[14]

VII.1.3 The IA content

Although the IA report on the whole is a clear and readable document which presents the information in a structured way, the section on objectives does not really contain objectives but rather conclusions, as is illustrated by the following extract:

> In line with enterprise policy the proposal will promote competitiveness because it encourages entrepreneurship, product and process innovation and facilitates access to markets. It will take away potential obstacles to competitiveness on the Internal Market and will benefit of small and medium sized enterprises.[15]

This could perhaps be explained by the fact that the final IA report was drawn up after a long series of studies and reports used in the consultation process (see VII.1.2), although the section on options is presented as starting from scratch. Five options are identified at the outset:

1. National fixed sizes with obligatory acceptance by any Member State.
2. EU fixed sizes, maintaining the current mandatory sizes existing for some products, e.g. wine and spirits as well as maintaining existing ranges which contain about 15 sizes.
3. EU fixed sizes but limiting the range of sizes within which sizes are fixed so that it includes only the most sold sizes. Outside the range sizes would be free.
4. Free sizes allowing producers to pack in any size in function of demand without interference from any authority.

13 EC Report 'Pack sizes in the EU' (2004).
14 *Ibid.*
15 SEC(2004) 1298, p. 4.

5. Voluntary standardisation in the context of free sizes allowing stakeholders to standardise package sizes where it is deemed useful.

Yet, not all of these options represent real possibilities. The IA quickly discards fixed sizes established at the national level as they would hinder trade on the EU market.[16]

Rather than analysing the various impacts per option, the IA jumps straight to a comparison, speaking of 'criteria' instead of categories of impacts. The IA mostly consists of logical, qualitative reasoning supported by some numbers, but also by 'case studies'.[17] Vibert's scorecard singled out this case as the only IA to calculate the net benefit of regulation as similar to that of non-regulatory options.[18] Vibert is somewhat critical of the method used for quantification as the investment impact of allowing for free choice is treated as a cost, but consumer benefits from wider product choice are not identified or quantified. In the final table of the IA report it is acknowledged that consumer impacts are not monetised, a practice that is preferable to just mentioning the costs and completely ignoring the benefits as some IAs do. Besides the transparency surrounding the existence of this data gap does make it easier for those questioning the results of the IA to step into the process with their own data which the European Parliament promptly did (see VII.1.4).

The data have also been scrutinised during the iterative consultation process which was very much integrated with the IA process. In particular, the numbers put forward by one producer who wrote a letter on the burdens he expected to encounter after the pack sizes were liberalised, were used for the calculations of each sector that demanded fixed sizes. The results of this calculation were put in a schematised overview, making it easier to trace differences of opinion to quantitative assumptions. When during the consultation one sector gave – marginally – different costs, these were used as the basis for a sensitivity analysis. This analysis is included in the IA and reveals how the total costs per sector would change after a shift in the initial assumptions.[19] Although the method of using the data provided by a representative of one sector to calculate the costs of liberalisation for all sectors is questionable in itself, it matters a lot less when the sectors concerned have been given the chance to correct the numbers, as was the case here. In fact, this method could even be a proportionate way of achieving some quantification, as long as the IA is transparent on the issue. The IA report identifies a preferred policy option:

16 *Ibid.*, p. 6.
17 *Ibid.* quoting A. Peterse, L. Nijhuis, A. Palmigiano, 'Regulation and Innovation in the area of pre-packaging sizes', F. Leone (ed.), EC DG JRC-IPTS Technical Report Series (Seville, 2002).
18 Vibert (2004), p. 9.
19 Interview Commission official D.

> The impact assessment of policy alternatives has shown free sizes to be the most favourable option as it allows full competition for industry and freedom of choice for consumers without compromising the environmental aims of the Community.[20]

However this preferred option of deregulating pack sizes is mitigated by taking on elements from the fixed sizes option no 3:

> [I]t also appeared that there might be sectors for which regulation on the basis of total harmonisation should be maintained. Fixed sizes may allow to offset disproportional buyer pressure from large distributors, like supermarkets, on small and medium sized enterprises and a sudden change to free sizes would cause industry to incur excessive costs, notably in sectors with structural low demand growth that are accustomed to fixed sizes.[21]

The IA report concludes that mandatory ranges can be justified for the sectors where the Community regulator had already fixed harmonised mandatory sizes: wine, spirits, soluble coffee and white sugar. It should be noted that maintaining fixed sizes in the sugar sector was still a leftover from a promise made to Parliament in a conciliation procedure in the late 1990s.[22]

> In these sectors it would suffice to fix by law a limited number of sizes which are most sold to consumers. Given more time these sectors may be assumed to be able to adapt there processes to more flexible production and it would seem that the lifetime of investments (20 years) should suffice as the period during which sizes remain fixed by law.[23]

Not mentioned in the IA report, but part of the initial proposal are the fixed aerosols sizes which the Commission also proposes to maintain although 'in contrast to regulation of pack sizes, which aims to protect legitimate economic interests, aerosols sizes and filling levels are dictated by assurance of safety'.[24]

Does this mixed outcome invalidate Baldwin's hypothesis that IA is not capable of fostering 'smart regulation'?[25] Not necessarily, because in this case certain qualities of the pre-packaging assessment which are not archetypical 'IA qualities', make the 'pick and choose' preferred policy option a reality.

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20 SEC(2004) 1298, p. 15.

21 *Ibid.*

22 During the conciliation on the sugar directive. Council Directive 2001/111/EC of 20 December 2001 relating to certain sugars intended for human consumption, OJ L 10, 12 January 2002, pp. 53–57.

23 SEC(2004) 1298, p. 15.

24 COM(2004) 708 final, p. 5.

25 By 'smart regulation' Baldwin means a combination of different regulatory techniques in one framework in order to achieve 'a reflexive, dynamic approach in which regulatory strategies are constantly revised and 'tuned' to changes in circumstances, preferences and so on'. Baldwin (2005).

Because at no point aggregate costs and benefits are used to compare options, it is possible to recommend an option that has not been analysed as such in the IA. Baldwin had a more rigid type of IA in mind, one rather close to the 'truth to power' model (see II.3.1), in which the requirement to carry out thorough and detailed analysis gives bureaucrats an incentive to restrict themselves to relatively simple regulatory options. But since in the pre-packaging IA cost-benefit analysis has been replaced by thorough consultation and qualitative reasoning, there was space for the (politically) rational option of a mixed approach, allowing for exceptions on a sectoral basis, in anticipation of the inevitable compromise.

VII.1.4 The use of IA

Aid to internal decision-making in the Commission

The IA results have influenced the internal decision-making in the Commission. On the bureaucratic level the IA process has brought increased awareness of regulatory alternatives,[26] matching the preference for a lighter regulatory touch at the political level. In the last stage of policy formation the Better Regulation agenda inspired the political choice to simplify whenever possible. In other words the Commission's stance was 'deregulate when in doubt', a rule of thumb applied even more rigorously in the revised proposal that the Commission was to present in April 2006[27] in which only the 'clear cases' – wine and spirits – retained their fixed sizes. It was the distinct impression of those within the Commission directly involved that the preparation was more professional and more transparent because of the IA process. In particular, stakeholder interests have not only been noted but also analysed in the framework of economic processes and policy goals.[28]

A 'counter-IA' from the European Parliament

The Commission IA was well received in Council[29] (see also the next section) but less so in the IMCO Committee of the European Parliament.

> The members of the Committee on the Internal Market and Consumer Protection *immediately questioned the relevance of the proposal and the quality of the impact study on which it is based*. I was therefore led to propose that other basic products be

26 Interview Commission official C.
27 COM(2006) 171. See section 'The Commission and the Council agree on further 'deregulation'.
28 Interview Commission official C.
29 Interview national official C.

> subject to mandatory ranges. They are coffee, butter, rice, pasta and drinking milk.[30]

The rapporteur for the Parliament, MEP Jacques Toubon, member of the IMCO Committee, argued that in the sectors of drinking milk, butter, ground or unground roasted coffee, dried pasta, rice and brown sugar mandatory sizes are warranted. Whereas in the case of the sectors included in the Commission proposal it is a matter of maintaining or restoring previously existing pack sizes, new pack sizes would have to be introduced by many countries for the sectors Toubon proposed to add to the list of exceptions. His basic argument runs as follows: since these products are part of the average consumer's daily diet, they tend to be consumed in large quantities. Without a restricted number of nominal quantities in which they can be sold, consumers and especially the weakest among them, could be tricked into paying more for products when for instance the packages contain less than they expect. The Commission and the European Parliament also had different views regarding the period for which the exceptions should apply. Whereas the Commission wanted a 20 year limit on all exceptions, IMCO committee members expressed themselves in favour of a clause that would oblige the Commission to revisit the legislation after eight years since – they claimed – no one can predict what the market will look like in 20 years time.

The IMCO Committee decided in June 2005 to commission an impact study before the first reading of the directive on pre-packed products.[31] The study on proposed amendments was contracted out to Ergo Communications, a consultancy company belonging to the Global Consulting Group. The IA study was prepared before the adoption of the Common Approach[32] in November 2005, so there were no 'common principles' or 'traffic rules' to guide the process. Leaving aside the experiments by the Environment Committee (see IV.2.4), this is the first major example of an IA on substantive amendments and also the first IA the Parliament is promoting as such.[33] The reasons which led the European Parliament to conduct a real IA – its first ever – are quoted in clear terms in the IA study itself:

> The European Parliament (EP), while in principle agreeing with the European Commission's liberalisation approach (Draft report for the IMCO Committee, Explanatory Statement, page 16), tends to believe that mandatory pack size ranges should continue to apply to certain 'basic products'. *The EP thinks that the European Commission's impact assessments – which led the latter to favour the liberalisation scenario – did not sufficiently take into account the impacts of this policy option on*

30 Toubon in the plenary debate on 1 February 2006. Emphasis AM.
31 EP Impact Assessment Study Pre-packaging (2005).
32 Common Approach to Impact Assessment (2005).
33 E.g. at the conference on Impact Assessment organized by the European Commission on 20 March 2006.

> *consumers (in particular vulnerable consumers) and small and medium sized enterprises (SME)*. The EP has therefore commissioned this impact assessment (…).[34]

MEP Toubon clarified his motives further in the interview conducted for this research project, stating that the initiators of the parliamentary IA wanted to make clear that even in an era of Better Regulation it is still necessary to make the case for liberalisation. In his opinion, if the Commission sends impact assessments to Parliament that are deemed unsatisfactory, the possibility to have an IA carried out provides the Parliament with the opportunity to prove the Commission wrong.[35] The explicit objective of the study as stated in the IA report[36] drawn up by the consultants is to

> enable the Honourable Members to fully understand the positive and negative impacts (costs and benefits) – in economic, social and environmental terms – of their favoured policy option and of the amendments they have tabled in first reading (at the committee stage), and to gain insight into alternative policy choices (full liberalisation; no change scenario).[37]

The following conclusion is included in the executive summary.

> Our weighted findings support the policy option favoured by the European Parliament – the *a priori* liberalisation of pack sizes while retaining fixed ranges of pack sizes for certain 'basic products' (pasta, milk, butter, coffee and sugar). As the analysis and the impact assessment model show in greater detail, a liberalisation of pack sizes in these product categories would, overall, be a disbenefit. *However, the balance – based on our initial weightings, which may be varied according to the political preferences of the Honourable Members – is a very narrow one*.[38]

This conclusion is remarkable in more than one respect. First of all it becomes clear that a preferred policy option was identified before the IA was carried out and the assessment was then used as some kind of 'ex post check'. This is a variant of use of IA that can be place somewhere in between the 'truth to power' prototype (see II.3.1) and the 'reason-giving' model (see II.3.2). This is the model that will often have to be followed for parliamentary IAs which are after all on 'substantive amendments'. But which consultancy firm would stand firm enough and present its client with evidence that disqualifies the preferred option? Compared to the highly politicized context in which amend-

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34 EP Impact Assessment Study Pre-packaging (2005). Emphasis AM.
35 Interview Jacques Toubon. Original statement in French; translation AM.
36 All Commission document that were submitted to the consultants as part of the IA work, were quoted with the names of the responsible Commission officials. This can be taken as a sign that this IA process took place before the (inter-)institutionalisation of EU IA; clearly publishing the IMCO IA was not on anyone's mind.
37 EP Impact Assessment Study Pre-packaging (2005), p. 6.
38 *Ibid.*, p. 10. Emphasis AM.

ments are drafted, the early stage of policy-making in the Commission takes place in the relative vacuum that allows for an IA to explore more options than a parliamentary IA ever could.

Second, the mentioning of 'weighted findings' warrants further explanation. By this the consultants mean the experimental impact assessment model they developed especially for this study, designed 'to enable a holistic, balanced view of the impacts on consumers and manufacturers, following the request of the Honourable Members to provide them with a 'synthetic picture' and reflecting their specific needs by being short, concise and easily accessible but at the same time comprehensive'.[39] Further on in the document this is clarified:

> One problem with impact assessments is that some elements, for example the impact on manufacturers' finished goods stock, are fairly easy to quantify, yet not of great social or economic importance. Other elements, for instance the impact on vulnerable groups of consumers, can be of immense social and political importance, yet very difficult, or even impossible to quantify in monetary terms. In order to get around this problem a new approach to impact assessment has been developed and applied to the issue of fixed packaging sizes.[40]

The result of this experiment is a list of 35 hypothesised impacts, 14 of which are presumed to be socially or economically beneficial (e.g. more consumer choice), and 21 of which are presumed to be detrimental (e.g. confusion for partially sighted people).[41] For each of these hypotheses it is indicated from which among five perspectives they are presumed to be beneficial or detrimental. The perspectives included are: 'competitiveness', 'consumer choice', 'consumer protection', 'vulnerable groups' and 'cost structures'. In the next column a 'verdict' is given on whether the hypothesis is true or false with 'neutral/not significant' also being an option. Then, in the final column the 'score is presented', consisting of the 'verdict' multiplied by the political weighting factor the study attributes to each of the five perspectives (three for 'competitiveness' and 'vulnerable groups', two for 'consumer choice' and 'consumer protection' and one for 'cost structures'). The authors of the report explicitly state that the weighting factors can be altered in accordance with the political preferences of the decision-maker, even encouraging MEPs to do so in the 'interactive' Microsoft Excel spreadsheet that was allegedly attached to the IA study.[42]

39 *Ibid.*, pp. 12-13.
40 *Ibid.*, p. 14.
41 *Ibid.*, p. 45.
42 *Ibid.*, p. 48.

> For example, if competitiveness is not considered to be a very important factor but consumer protection instead is, the values could simply be changed which would ultimately have an effect on the overall result.[43]

And the consultants:

> (…)believe that one great advantage of the impact assessment model set out here is that the Honourable Members' political convictions can easily be incorporated in the model structure by changing the initial weighting we have given to specific impacts and groups.[44]

Although this is a very creative attempt to carry out multi-criteria analysis in a transparent way, the method is also naive in its ambitions. The main problem is that the underlying methodologies to gather data that have been used to establish to what extent each of the 35 working hypotheses are true or false appear very limited in scope. But the analysis of scientific studies and the analysis of the submissions stakeholders made during the European Commission's consultations and those sent to the European Parliament's Rapporteur are not the most problematic parts. There is an additional methodological problem with the 'shop survey', an inventory of a limited range of products in a small number of supermarkets in Brussels. The purpose of this shop survey was to establish whether a free choice of sizes actually leads to more pack sizes within a brand, or within a category. Brussels was taken as a representative city and in nine supermarkets belonging to six different chains seven fixed-size product categories were surveyed. These were all product categories for which the European Parliament considered maintaining mandatory ranges of pack sizes, but five non-fixed size categories of similar products were used as a control group.[45] Such a limited survey can hardly serve as a basis for the conclusion 'that free sizes give more pack size choice but less brand choice' as this IA report argued.[46]

Also, the worth of the 'evaluation of answers to questionnaires sent to organizations representing consumers and manufacturers'[47] as data that can be used in the weighting model presented above, is questionable. In the questionnaire stakeholders are asked whether they agree or disagree with the hypotheses formulated by the consultants. There is no valid way of converting the opinions of consumer organizations on these issues into statements on

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43 *Ibid.*

44 *Ibid.*, pp. 12-13.

45 *Ibid.*, p. 15.

46 *Ibid.*, p. 17.

47 *Ibid.*, pp. 14-15. The consultants carrying out the IA received answers to the general consumers' questionnaires from five (out of the nine agreed) countries (Austria, Czech Republic, France, Italy, Poland) and to the 'vulnerable consumers' questionnaires from four countries (Austria, Czech Republic, Italy, UK).

whether these hypotheses are true, as this IA study attempts to do. Admittedly, the IA study is careful to draw attention to the fact that consumer benefits are particularly hard to quantify, but this problem is not solved by peppering the questionnaire with questions such as '[i]s there any way to put a monetary value on the impact on consumers?' or 'overall would you say that, for consumers, the net overall impact of liberalising pack sizes would be [please select one]'.[48] The methodological problem in this IA study is related to the issue of whether – faced with 'hard to quantify' benefits – it is better not to quantify them at all or to make an attempt. The Commission IA takes the former approach and has received criticism from Parliament for this choice. However, the parliamentary IA study itself is an unfortunate example of the latter approach for reasons set out above.

Doubts about the objectivity of the Commission's consultation were in fact an important reason for the IMCO Committee to commission its own IA. Toubon's low opinion of the Commission's consultation was also expressed in his report where he proposed to delete the qualification 'wide' to describe the consultation. Rapporteur Toubon clarified his objections as follows:

> The Commission has simply said on the basis of the IA that the consumer organizations do not really take an interest, that this proposal will increase competition between producers and distributors and that there is not really an impact on consumers. And all of this on the basis of an IA of which we have become aware that only a few rare consumer organizations have responded to the Commission and that professional organizations have only be consulted – through a long process – in a few sectors. Other sectors, like rice and pasta, have not had a discussion with the Commission. So the Commission has satisfied itself that these other sectors have no problem and that it is appropriate to abandon the obligatory sizes after 10-15 years.[49]

The Commission insists that the sectors of which Toubon claims that they were deprived of the chance to voice their opinion were given sufficient opportunity to react but simply did not show an interest because they were happy with liberalisation.[50] This situation does raise the issue of whether reporting on consultation should be even more extensive than it currently is and include for example the 'no-replies'. Indeed the problem of lack of transparency in reporting not only on results but also on process is also present in the parliamentary IA. Consultation of stakeholders was an important part of the terms of reference for the parliamentary study, and is an important source of information for arriving at the 'verdicts' in the model described above. And yet it seems to suffer from the same flaws that the Parliament reproaches the Commission for. For instance it is not clear whether the consultation of industry

48 *Ibid.*, p. 55.
49 Interview Jacques Toubon. Original statement in French; translation AM.
50 Interview Commission official C.

stakeholders was an open one or whether a selected number of organizations were approached. For the consultation of consumer organizations it is clear that only those from a list of 'agreed countries' were consulted, but the selection criterion for arriving at this list or even the parties that were involved in the agreement are not given and therefore it is not possible to establish whether there has been a bias. It is clear that a) the national origins of the consumer organizations consulted roughly coincides with those of the industry representatives that submitted position papers (although French industry stakeholders are a disproportionate majority here) and b) the only overlap between the 'agreed countries' from the parliamentary IA (Austria, Czech Republic, Denmark, France, Hungary, Ireland, Italy, Poland and UK) and those who responded to the Commission consultation (Greece, Estonia, France (two times), Lithuania, Netherlands and UK (two times)) consists of the French and the British, clearly the most active consumer organizations. Whether the consumer organizations consulted for the parliamentary IA have been selected to match the national origins of the industry consultees or not remains unclear.

Which national organizations are consulted matters greatly though, as the interests of stakeholders vary from one country to another, even within the same sector, because of the differences in existing national regulatory frameworks. Regulation of pack sizes is also an area prone to rent-seeking by industries claiming to seek to preserve their national traditions (e.g. 'the British pint of milk') but are mainly interested in disadvantaging their European competitors. A salient observation in this regard – suggesting consultation bias – is that the seven dairy associations who sent a letter to the Institutions to argue against Toubons amendments, come from different countries from the five dairy associations whose responses have been taken into account in the parliamentary IA.[51]

Toubon indicated that he feels that the Parliament still has a weak position in informal discussions with the Commission which possesses the relevant information:

> If we want to place the European Parliament and the Commission on an equal footing we have to get out of a situation in which we have to ask the Commission for information which means we are in a position of dependency.[52]

Yet Commission maintains that given them all the material, a claim that is at least not undermined by the parliamentary IA study itself, which mentions that Ergo Communications carried out an 'analysis of the submissions stakeholders made during the European Commission's consultations and those sent to the European Parliament's Rapporteur'.[53]

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51 EP Impact Assessment Study Pre-packaging (2005), pp. 18-19.
52 Interview Jacques Toubon. Original statement in French; translation AM.
53 EP Impact Assessment Study Pre-packaging (2005), p. 15.

There are clear signs that the first parliamentary IA has been used in the decision-making in the IMCO Committee and it has subsequently been referred to extensively in legislative debates and in the relevant legislative documents. The decision on the adoption of the Toubon report was postponed at least once because the results of the impact assessment were not yet known.[54] His amendments were largely accepted by the IMCO Committee and later also in the plenary. The new recital proposed in the report by the rapporteur claims that

> a study devoted to the impact of the Directive on the most vulnerable consumers (the elderly, the visually impaired, the disabled, consumers with a low level of education, etc.) has *confirmed the theory* that deregulation of packaging formats would entail major drawbacks for these consumers, while triggering a reduction in the number of brands offered to the consumer and hence reducing choice and, consequently, competition in the market.[55]

This is a strong claim to make on the basis of the IA study that is weakened by its own methodological ambitions. Although the IA report itself uses rather careful wording (e.g. by acknowledging the 'narrow balance' between regulation and deregulation and by repeatedly mentioning that 'some but not fully conclusive evidence' has been found), no such caution is observed by the rapporteur when he writes that

> the findings of this study *concluded* that the majority of consumers are not aware of unit prices; furthermore, the findings *challenge* the Commission's theory that deregulation would automatically entail a boost to competition in the marketplace since the number of brands on offer to consumers would be reduced consequently. The study *provides clear backing* for the proposal to derogate from liberalisation for certain basic foodstuffs in order to protect the most vulnerable consumers. It also *demonstrates* that the liberalisation of packaging guarantees neither increased competition between producers nor increased choice for consumers nor a satisfactory response to the needs of the largest and weakest categories of consumer.[56]

In the plenary session on the Toubon report on 1 February 2006, the rapporteur concluded his speech as follows:

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54 Document from the Secretariat of the Committee on the Internal Market and Consumer Protection, Brussels, 12 July 2005 containing a list of decisions of the Meeting of the Bureau and Coordinators of Monday 23 May 2005, which states that the Coordinators agree to postpone the adoption of the report of Mr Toubon to 22 November, "pending receipt of the Study commissioned on Impact Assessment of the amendments tabled". See http://www.europarl.eu.int/comparl/imco/coordinators_decisions/050523_coordinatorsdecisions_en.pdf (last accessed 26 March 2006).

55 EP Draft legislative resolution Pre-packaging (2005).

56 *Ibid*. Emphasis AM.

> I will highlight three factors: *an impact study that is funded by Parliament itself and that depends neither on the Commission nor on pressure groups, which is a first*; a concept of 'better lawmaking' inspired only by the interests of our fellow citizens and not by an ideological attitude; and a concern to retain our national cultures, because our nations are very attached to their food traditions and to their consumption patterns.

Yet, instead of convincing the Commission of the merits if the proposed amendments the IA gave rise to a clear condemnation by Vice-President Verheugen who came to defend the Commission's proposal:

> *The Commission questions the justification for regulation in these sectors*. European industry, with the exception of the coffee sector, is not in favour and consumers have not requested regulation that limits their choice. The proposed amendment would imply that a number of products that are placed on the market today would disappear. Furthermore, it would also mean that Member States that never had regulation or had abolished it would have to re-introduce regulation on package sizes. *This is contrary to the political aims of better regulation and simplification* and does not protect consumers. The Commission appreciates that the Parliament has carried out an impact assessment of these amendments. This initiative reflects the Commission's common concern for better regulation and simplification.[57]

Not all MEPs agreed with Toubon's attempt to introduce exceptions to liberalisation for more sectors. John Purvis, who drafted the opinion of the Committee on Industry, Research and Energy (ITRE) applauded 'the Commission's praiseworthy attempt to reduce unnecessary regulation' and added:

> [W]e in the Committee on Industry are disappointed to see proposals from that committee to introduce fixed, harmonised, mandatory sizes on a whole range of staple products which have not previously been so harmonised. We have labelling requirements. We prohibit misleading advertising. EU legislation requires unit pricing so that the price for a standard amount must be displayed, and this helps consumers to compare prices fairly. The ability to decide freely on package sizes is in the interests of the smaller business, the new entrant, the innovative enterprise and, therefore, also in the interests of the consumer.

But a member of the same political group (PPE-DE), Malcolm Harbour, defended the parliamentary IA of the IMCO Committee of which he is a member:

> [The study] indicated that despite the fact that there would be more complexity, the economic analysis demonstrated that the competitive effects were comparatively small and accepted the view of the rapporteur that there were consumer benefits to offset it.

57 Emphasis AM.

This discourse is reminiscent of the use of IA as 'reason-giving' tool (see II.3.2) that defends the choices of the legislator, rather than a 'truth to power' (see II.3.1) or 'highlighting trade-offs' approach (see II.3.4). Harbour added that the IA 'has made the Committee on the Internal Market and Consumer Protection the first committee in Parliament to commission an impact assessment where we have chosen – in this case in the interests of consumers – to add to the burden of regulation that the Commission has proposed'. Could 'adding to the burden of regulation' be a way of interpreting the criterion that an amendment has to be 'substantive' to warrant a parliamentary IA?

Toine Manders, speaking on behalf of the ALDE group called it 'unfortunate (…) that we have not opted for better legislation and deregulation as the Commission proposed, and we regret the proposals for exceptions.' For the ALDE group pre-packaging regulation is a topic for deregulation *par* excellence as it is deemed 'unnecessary for Europe to get involved in matters such as the measure of coffee or milk'. The other side of the political spectrum agreed with him on this: 'There is a danger of matters becoming rather ridiculous when the EU goes in for such things', said MEP Carl Schlyter, on behalf of the Verts/ALE Group. He conceded that 'it is, in truth, not often that I am able to agree with the Commission concerning liberalisation projects, but this is a sensible form of liberalisation'. Significantly he went on to state:

> I see that Mr Toubon has done some serious work and carried out an impact assessment, but *that is not sufficient reason for issuing regulations at EU level*.

Confusion and disagreement regarding the actual impacts of the proposals persisted also among MEPs from the same Member State. Whereas Swedish conservative MEP Charlotte Cederschiöld (PPE-DE) spoke of 'rescuing Swedish milk packs', a Swedish Social Democrat Anna Hedh (PSE) said that she was not convinced any benefit for consumers would arise from Toubon's amendments:

> On the contrary. If the rapporteur's approach were to meet with sympathy, it would involve major conversion costs for many European companies, and this without the groups we say we represent even needing or necessarily even desiring the changes. For example, the Swedish Consumers' Association, which works actively with quite a few cooperation groups and associations on precisely these issues to do with packaging, has, on the basis of our contacts with the Association, never heard any wishes expressed concerning fixed pack sizes. Moreover, the EU's institutions would not be complying with their ambition to improve the quality of legislation by avoiding detailed regulation.

Right before the vote on 2 February 2006 MEP Toubon invoked the first parliamentary IA one more time:

> Mr President, I should like simply to point out that the Commission proposal that consists of retaining mandatory packaging ranges for a number of staple goods, in the interest of consumers, is a coherent one. On the other hand, the position that consists of accepting the Commission's plan to retain certain mandatory sectors, while rejecting the Commission proposal, is not coherent. (…) In the interest of consumers, and in accordance with the independent study commissioned by the European Parliament for the first time in its history, I therefore recommend voting in favour of the entire set of amendments tabled by the Committee on the Internal Market and Consumer Protection, which adopted them by 28 votes with one abstention.

In the debate several references were also being made to the fact that the European Court of Justice takes the average consumer as a starting point[58] whereas many MEPs feel that it should be the disadvantaged consumer instead. Although this particular dispute was not resolved, the issue does seem to have strengthened those favouring liberalisation in their conviction of having reason on their side.

The Commission and the Council agree on further 'deregulation'

According to Toubon the case of pre-packaging shows that we are in a new era in which the Parliament is no longer automatically giving in to the proposals of the Commission just because the Commission has the means and the expertise. He added:

> [T]hese days the Parliament adopts political positions like before, favourable or unfavourable positions on the basis of Commission proposals, but it also has the capacity to contest the premises, the very foundations of Commission proposals and it can incorporate its own desired elements.

Yet in this instance the extra IA study did not help in convince the other Institutions, quite the contrary it seems. Toubon recounted how the IMCO Committee held several meetings with representatives of the Commission and the Council UK Presidency. At a certain moment he had the impression that agreement was within reach as both the Council and the British Presidency wanted to settle the matter before the end of the year,

58 *Gut Springenheide GmbH and Others v. Oberkreisdirektor des Kreises Steinfurt-Amt für Lebensmittelüberwachung*, Case No. Case C-210/96 [1998] ECR I-4657.

> but then I think the Commissioner made up his mind and took position. He had decided he wanted heavy liberalisation and apparently instructed his services not to accept any compromises.[59]

After the Commission took strong position against the amendments, supported by a number of delegations, the UK Presidency withdrew its compromise proposal. This is how Toubon explains the result of the vote in the EP plenary: by that time everyone knew there was not going to be a compromise in first reading, so the general feeling that the Parliament might just as well entrench itself in the own position in anticipation of the second reading.

The overview produced by the UK Presidency reports that the Commission IA on pre-packaged products has been used in the first working group discussion on 15 July 2005.[60] The IA produced by the European Parliament was explicitly presented to the Council as a 'counter-IA'.[61] It was discussed in the Working Party, but not too extensively since by then it was already clear that agreement in first reading was highly unlikely.[62] Also, the IA seems to have weakened the EP's case rather than strengthen it. The qualified majority in favour of the Commission proposal in COREPER in late November 2005 was rather large. Although Belgium and Germany had been toying with the idea of introducing more exceptions to the liberalisation, in the end only France and Italy were in favour of adding milk, butter and pasta to the list of regulated sectors.

After a few early indications from the side of the Commission, even before the vote in the IMCO Committee, that it wanted to get rid of the exceptions for soluble coffee, sugar and aerosols[63] as well, the Commission put forward a new proposal[64] thereby deviating from the earlier agreement with the Parliament regarding sugar. Although the amended proposal is not accompanied by an impact assessment, the Commission's new stance is justified partly with reference to the Parliament's IA and how it has failed to convince the Commission.

> The Commission does not accept amendment 4 which adds a new recital saying that a 'study devoted to the impact of the directive' shows the relevance of fixed sizes for vulnerable consumers for the following reasons:
> · The reference to 'a study' is too vague.

59 Interview Jacques Toubon. Original statement in French; translation AM.
60 UK presidency – BR progress report (2005).
61 Interview national official C.
62 *Ibid.*
63 This was supported by the aerosols industry which argued that the developments regarding the intended amendment of the Aerosol Dispensers Directive warrant the abolishment of fixed nominal quantities for aerosol containers.
64 COM(2006) 171.

- The impact study by EP did not make this point convincingly. The Commission impact assessment does not support conclusions of the EP impact assessment.[65]

And further on:

> The Commission does not accept amendment 5 on the grounds that there is no evidence that liberalization gives rise to a proliferation of pack-sizes and market complications; in particular not in the sectors that Parliament wants to add. Nor is it established that there is an impact on the environment.[66]

The Council subsequently – in its Competitiveness formation – reached a common position on 25 September 2006, supporting the Commission's modified proposal on condition that for certain sectors Member States would be allowed to maintain existing national sizes for domestic production in some sectors for a transitional period.

Second reading: a compromise in the making

At a speech before the IMCO committee in September 2006 Vice-President Verheugen again resorted to Better Regulation rhetoric when he anticipated the second reading of the pre-packaging dossier:

> A last word in this context on the Packaging Regulation. In its amended proposal, the Commission accepted all Parliament's amendments, with the exception of those attempting to introduce EU sizes into new sectors or to decrease the sectors coming under the scope of the Directive. In the light of our simplification programme in particular, this would give all the wrong signals. Should we patronise businesses and consumers in this way? I expect that the Council will take the Commission's line in its common position, and I would be grateful if your committee could support the amended Commission proposal in its second reading, not least for reasons of simplification and better lawmaking.[67]

Repeating once more how the proposal has become a test case for its strategy on Better Regulation, the Commission decided to support the common position, but subject to certain 'joint declarations'.[68] These joint statements by the Commission and the Council stipulate that any phasing-out applied to certain sectors by Member States may not refuse, prohibit or restrict the placing on the market of products legally marketed in another Member State on grounds

65 *Ibid.*
66 *Ibid.*
67 Speech/06/500, Günter Verheugen Vice-President of the European Commission responsible for Enterprise and Industry Exchange of views of Vice-President Verheugen with the Internal Market and Consumer protection Committee (IMCO) European Parliament, 14 September 2006.
68 COM(2006) 811 final, p. 4.

relating to the nominal quantities of the package. Nor can any new rules for nominal quantities of packages be introduced by Member States in the sectors to which the phase-out applies.

From the report which rapporteur Toubon prepared for the second reading the clear contours of a compromise in the making emerge: transitional periods for the controversial sectors, combined with 'a tough review clause' that should prevent 'these sizes actually being deregulated at the end of the transitional period if an evident disturbance of the market is detected'.[69] Furthermore the report mentions enhanced encouragement for Member States to extend the unit pricing requirement to all types of retail outlet. Finally, it is clear that Toubon is not prepared to give up white sugar as the deal closed by the Commission during the conciliation on the sugar directive is reiterated. Also, a new product has appeared on the parliamentary wish list: 'at the request of the British manufacturers of pre-packed bread' it is requested that the 'Standard British Loaf' is maintained. This is justified by stating that the rapporteur and 'his colleagues from the UK' believe 'it is essential to maintain a range for this very particular and traditional type of bread that is popular in the UK',[70] a far cry from the justificatory rhetoric used during the first reading, when there was at least an attempt at IA-style reasoning. Although the salience of the IAs seems to have faded in second reading, the rapporteur does remind us of the institutional clash that occurred earlier on with the Commission:

> The Council has clearly sought a compromise position as against the Commission's outright refusal to maintain any type of mandatory size, except for wines and spirits. However, your rapporteur would have liked to see the Council go much further and move closer to our position which is based on the realities of the retailing and consumer sectors.[71]

In the final directive derogations for milk, butter, dried pasta and coffee are maintained until 2012 and for white sugar until 2013.[72] The British loaf of bread has been given in a place in the preamble and the whole text is peppered with promises of enhancing consumers' understanding of unit pricing, monitoring the market situation and reporting on effects.[73]

69 EP tabled legislative report pre-packaging, 2nd reading (2007), p. 9.
70 *Ibid.*, p. 10.
71 *Ibid.*, p. 9.
72 Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC, OJ L 247, 21 September 2007, pp. 17–20, Article 2.
73 *Ibid.*, preamble and Article 9.

VII.1.5 Synthesis

Both the Commission and the Parliament make use of Better Regulation discourse but the two Institutions arrive at different appreciations of what the ever elusive concept of Better Regulation means in this particular case. The Commission takes the view that whereas Better Regulation does not *necessarily* mean 'less regulation', in some cases – certainly including the pre-packaging dossier – it does. The European Parliament on the other hand, holds on to the view that Better Regulation has nothing to do with deregulation.

The two IAs that were made for the pre-packaging proposal actually have more in common than would seem from the fierceness of the tone adopted by each Institution when condemning the IA of the other. Both IAs try to get around the problem of a lack of quantified benefits by consulting stakeholders and – more importantly – by claiming to have the support of the consumers' organizations. Neither IA is of the kind that provides conclusive evidence, providing every opportunity for the Institutions to act in accordance with their general political stance on Better Regulation. For the Commission that means 'when in doubt, deregulate' and for the European Parliament it amounts to 'when in doubt, regulate'. Although there is some evidence that IA has improved the preparation of the proposal and has really 'structured the discourse' between the Commission and stakeholders, later on in the process the presence of IA seems to only have fostered hard bargaining instead of deliberation on the basis of arguments.

This case study illustrates once more that it is easy to criticize IA procedures on procedural grounds, certainly in the absence of agreement on concrete procedural standards, and difficult to use IA as the basis for substantive discussion. Clearly, 'one size fits all' does not apply; not only where pack sizes are concerned, but also when it comes to finding the appropriate methodology for gathering input for an impact assessment; what is good consultation to one actor is illegitimate cherry-picking to another. When only six consumer organizations out of the 25 Member States respond to the Commission's consultation of the European Consumer Consultative Group, is the conclusion warranted that 'the issue of pack sizes does not seem to be a major preoccupation of consumer organizations',[74] or is it a matter of a lack of resources on the part of consumer organizations that should have been compensated for more actively? And even if one takes the latter view, is consulting a list of consumer organizations from 'agreed countries' without disclosing the basis of the agreement the way to overcome this perceived flaw?

The conclusions of this section regarding the inter-institutional aspects of IA in this case are in line with those from the TEP external evaluation of the Commission's IA system (see III.4.3):

74 EC Report 'Pack sizes in the EU' (2004), p. 26.

> With regard to inter-institutional learning, particularly between the Commission and the EP, there may well be a lot more to be done. There is clearly some difficulty in moving from the professional process of an IA to the political process of voting in new legislation and Commission officials find themselves caught in this situation. One contributor summed up the dilemma by saying that, however good an IA, an economist needs to accept that the law reigns in the end. In this particular case, the fact that the EP decided to carry out its own IA seems to have led to a fraught relation to some extent.[75]

The references to IA in the legislative debates are dominated by the European Commission and the European Parliament accusing one another of consulting stakeholders in a too limited way. This mutual 'IA bashing' makes any open discussion on specific elements of the IA studies impossible. Whereas no IA system could – or should – change the political preferences of actors involved, in most models – and certainly in the highlighting trade-offs model – it is hoped that the use of IA can narrow down the scope for doubt. Potentially the type of modelling attempted by Ergo Communications could structure the discussion in a situation of political disagreement on the degree of 'de-regulation', as existed between the Commission and the European Parliament in the pre-packaging case. However, the clear limitations of the parliamentary IA in this case made it only too easy for the Commission to discard the study altogether.

Was the Parliament given insufficient credit from the Commission for initiating the 'first parliamentary IA'? A shared feeling that this was the case on the part of the Parliament may have been a factor in causing it to become even deeper entrenched in its 'counter-IA' thinking. Although the attempt did not succeed and was abandoned in second reading altogether it could be argued that Toubon has attempted to use IA as a 'trump' (see IV.2.4) or a 'shield' (see II.3.2) when he repeatedly claimed in debates that the IA had shown his amendments to be justified when in reality the evidence was flimsy. Perhaps one rather banal lesson to be drawn from this case is the following: since not many actors in the decision-making process actually read the report[76] it is very easy to appeal to the authority of an IA rather than to its content.

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75 The Evaluation Partnership (TEP) – Annexes case studies (2007), p. 291.

76 The interviewees in this case had all read the IA report, but in general it has emerged from interviews that many intended addresses of IAs do not actually read the report or even the executive summary, warranting the assumption that not many MEPs taking part in the debate would have read the IAs on pre-packaging.

VII.2 DATA RETENTION: WHERE IS IA WHEN IT IS MOST NEEDED?

From an IA perspective the case on the retention of telecommunications traffic data is perhaps more interesting for what it could have been than for what it actually is. The situation in which a Commission proposal which had an IA had to 'compete' with a third pillar proposal that was also on the table (without IA naturally) could have been an interesting setting for studying the role IA can play in determining the correct legal base. But the EU lawmaking process is not a social science laboratory and for various reasons articulated below, the IA did not have much of an impact at all. Still, it reveals how enhanced expectation caused by the existence of an IA can be damaging for the level of trust between actors in the legislative process.

VII.2.1 Background in brief

The Directive on Data Retention aims to harmonise Member States' national legislative measures concerning the obligations of the providers of publicly available electronic communications services or of public communications networks with respect to the retention of certain data which are generated or processed by them, in order to ensure that the data are available for the purpose of the investigation, detection and prosecution of serious crime, as defined by each Member State in its national law.

Inter-institutional decision-making in the data retention dossier was an instance of 'high politics' of the fiercest kind. The topic has all the ingredients for an intensive battle with high stakes on all sides: a justice and home affairs component, a security component (with a fundamental rights components inevitably attached to it)[77] and an internal market component. From an IA perspective one could say that a file like this could profit a lot from an integrated impact assessment, in particular from an overview of trade-offs across policy options. However the circumstances in which the policy developed did not give much space for such thorough assessment.

The dossier is one in a series of high-profile cases that gave rise to competence-related disputes between the Council on the one hand and the Commission and the Parliament on the other. The UK, France, Sweden and Ireland had put forward a so-called 'Third Pillar' proposal (a proposal on the basis of Articles 31 and 34 TEU) for a framework decision on the retention of data processed and stored in connection with the provision of publicly available

77 The prevailing opinion among human rights lawyers seems to be that data retention legislation, certainly 'blanket traffic data retention' violates Article 8 and Article 10 ECHR because "its harmful effects on citizens by far outweigh its benefits". See P. Breyer, 'Telecommunications Data Retention and Human Rights: The Compatibility of Blanket Traffic Data Retention with the ECHR' (2005) 11 *European Law Journal*, 375.

electronic communications services or data on public communications networks for the purpose of prevention, investigation, detection and prosecution of crime and criminal offences including terrorism on 28 April 2004 and a new proposal on 14 April 2005.

However, the Commission had indicated from the start that it would preclude putting forward its own proposal if an analysis showed that a 'First Pillar' instrument (legislation falling within EC competence) was more appropriate. The Parliament is almost by definition in favour of First Pillar instrument as this means the proposal has to be adopted in codecision. In this particular dossier the European Parliament adopted the resolution drafted by Alexander Alvaro (ALDE) as part of the consultation procedure which had already started for the Third Pillar proposal. The resolution firmly rejected the initiative of the four Member States on the grounds that it was disproportionate and incompatible with Article 8 of the European Convention on Human Rights. The Commission had decided to opt for a first pillar proposal as a replacement for the Framework Decision proposal in January 2005 and this decision was announced in May 2005 by Information Society Commissioner Viviane Reding.[78] On 21 September 2005 the Commission adopted such a proposal for a Directive on retention of communication data. The pressure to put in place legislation was enormous, especially after the terrorist attacks in London and Madrid. From September 2005 onwards the legislative process moved very fast, mainly because the Council and the European Parliament closed a deal that guaranteed agreement in first reading.

VII.2.2 The IA process

The proposal was not listed in the Commission Legislative and Work Programme (CLWP), but for political reasons it was not possible to get around performing an IA.[79] As part of its wider involvement in the dossier the Commission had already organized two meetings in the course of 2004: one with national experts from justice departments, the other also including industry representatives.[80] Several 'IA-type' studies had been carried out: a study from the Erasmus University commissioned by the Netherlands government,[81]

78 Http://www.euractiv.com/en/infosociety/parliament-data-retention/article-140229(last accessed 15 July 2007).

79 Interview Commission official D.

80 *Ibid.*

81 Erasmus Universiteit Rotterdam, *Wie wat bewaart die heeft wat. Onderzoek naar nut en noodzaak van een bewaarverplichting voor historische gegevens van telecommunicatieverkeer* (Rotterdam, 2005).

another Dutch study by KPMG,[82] several studies of German origin and a study funded by the telecommunications industry.

So when the impact assessment had to be prepared in the course of only a couple of weeks because of the time pressure, there certainly was material to draw on.[83] Also, because of the time pressure and the particular difficulty estimating economic costs associated with this subject, the authors opted for providing an overview of the state of knowledge on the subject, whilst indicating in which areas knowledge was lacking. The impact on fundamental rights – the main concern of most NGOs involved – was taken into account, but for new elements or a new consultation round there was no time.[84] There was no time either for establishing an Inter-Service Steering Group, currently a firm requirement of the impact assessment process. However, there was more informal cooperation. The lead Directorate-General was DG Justice Liberty and Security but the economic analysis was carried out by DG Information Society and the internal expertise on privacy was drawn from DG Internal Market.

VII.2.3 The IA content

The Commission impact assessment on the data retention proposal[85] starts by explaining that under current legal arrangements, operators do not have the need to store traffic data for billing purposes as they used to do. The problem to be tackled is thus that

> [i]f traffic data are not stored for billing or other business purposes, they will not be available for public authorities whenever there is a legitimate case to access the data.[86]

The IA report observes that a number of Member States have adopted, or planned to adopt, national general data retention measures[87] and then goes

82 KPMG Informatie Risk Management, 'Onderzoek naar de opslag van historische verkeersgegevens van telecommunicatieaanbieders, Amstelveen 2004. The KPMG report was criticised by civil rights NGOs as a "police wishlist, without any substantial evidence for the necessity of data retention". EDRI-gram, number 3.13, 29 June 2005, 'Dutch Study Fails to Prove Usefulness and Necessity of Data Retention'. See http://www.edri.org/edrigram/number3.13/retention (last accessed 25 May 2007).

83 Interview Commission official D.

84 *Ibid.*

85 SEC(2005) 1131.

86 *Ibid.*, p. 3.

87 'Compared to data preservation measures, which are targeted at specific users and for specific data, general data retention measures aim at requiring (some or all) operators to retain traffic data on all users so that they can be used for 'public order' purposes when necessary and allowed.' SEC(2005) 1131, p. 3.

on to justify the need for legislative action at the European level by referring to the European Council's Declaration on Combating Terrorism of 25 March 2004, Conclusions of the European Council of 16 and 17 June and the special Justice and Home Affairs Council meeting of 13 July 2005 following the London terrorist bombings. The tone throughout the IA is justificatory and the importance of traffic data to serious criminal and terrorist investigations is repeatedly emphasized. The last pages of the problem definition are dedicated to anecdotal evidence from other studies and the consultation conducted in 2004. The main objective is formulated in a self-referential manner:

> The overall policy objective of the proposal is to provide for a European wide harmonisation of legislation on retention of traffic data which balances in a proportionate manner the needs of law enforcement, the fundamental rights of the citizens and the interests of the electronic communications industry. This European wide harmonisation should furthermore be achieved on the appropriate legal basis in order to provide legal certainty to all involved.[88]

A long list of more concrete objective follows. However the impression that this IA has been carried out in a late stage of policy development and that it was made to fit the proposal rather than to challenge it, is confirmed in the next section on policy options. It states that a number of different policy options have been considered by the Commission but most were discarded at an early stage 'given the developments in this area over the past few years'. These discarded options include the 'do nothing' option, self-regulation and 'soft-law' approaches and for each of these a short justification is given as to why the Commission deemed it appropriate to discard it.

According to the IA, in case the Commission would do nothing either the problems described in the first section would 'in all likelihood continue to increase' or the Council would adopt a Framework Decision on data retention which 'would also be less than satisfactory from the Commission's point of view, mainly given the legal difficulties associated with this option'. This is hardly reasoning worthy of an impact assessment; the very least that could be expected is an estimation of the impacts 'doing nothing' would have so that these can be compared to regulatory options. Similar reasoning, using considerations from outside the IA framework, has been used to discard self-regulatory options. The IA concludes that despite debates no common self-regulatory solution has emerged and, besides, 'the European Council has already called for a legislative proposal in this area'.[89]

There was no space for the IA to substantively engage with the question of the legal base as the Legal Service had already produced and made public a note for the Article 37 Committee containing the Commission's argument

88 *Ibid.*, p. 7.
89 *Ibid.*, p. 10.

for adopting a proposal under the First Pillar.[90] Thus the Commission's legal basis argument was merely repeated from this note, namely that 'a legal basis for imposing obligations on electronic communications service providers can only be found in the first pillar, whilst regulation on access to and exchange of such data by law enforcement authorities can only be built upon a third pillar legal basis'.

All key issues, including why an instrument on data preservation – which was suggested by industry and data protection authorities and mentioned in the IA as 'a final option' – was considered inferior to data retention, are discussed in a very qualitative manner. The IA discusses the impacts of the proposal and explicitly acknowledges that it deviates from the IA template by doing so. On a positive note, the IA describes the various categories of costs although it does not provide any quantification, apart from some 'quantitative examples' which never transgress the level of anecdotal evidence already used in abundance for the problem definition.

Finally, the section on proportionality is mainly an overview of the discussion on this point and the indications given by the Commission on the basis of which it claims to be 'confident that the bodies mentioned will be able to revisit their position'[91] are merely statements that the proposal *is* proportionate. How could it be else, comparative data on various options, capable of showing that there is no less intrusive means of reaching the policy objectives, is lacking?

VII.2.4 Use of IA

Aid to internal decision-making in the Commission

Within the Commission services the IA was seen as useful for the legitimation of the proposal, but also for the internal political discussion. Despite the lack of ISSG the perception of the interviewee was that IA helped structuring the internal conversation on the proposal. In particular DG Information Society and DG Justice Liberty and Security had some conflicting interests and ideas, mainly relating to the desirable length of the retention period. The IA was also seen as a useful supplement to the explanatory memorandum which can only be a maximum of ten pages in view of the translation requirements. Thus, IA becomes a useful tool for explaining 'the whys and the wherefores' of the proposal.[92]

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90 SEC(2005) 420,'Projet de décision cadre sur la conservation des données – Analyse juridique', 22 March 2005.

91 SEC(2005) 1131, p. 21.

92 Interview Commission official D.

European Parliament: much ado about nothing

Whereas IA-related *discourse* was very present in the legislative deliberations in Parliament, the IA *results* from the Commission report were almost invisible. Although the MEPs charged with this proposal definitely made a big issue of the necessity of impact assessment for a file like this, the impression on the part of the Commission was that its IA was just not taken up in the relevant decision-making venues.

The Commission proposal on data retention was forwarded to Parliament on 21 September, together with the impact assessment.[93] The British Presidency informed the Conference of Presidents the Parliament immediately that it was interested in reaching a compromise that would see the Data Retention Directive adopted in first reading before the end of 2005. The Conference of Presidents agreed, which meant that the last opportunity to adopt a compromise was in the part session week from 12 to 15 December 2005. This resulted in an 'extremely accelerated legislative procedure', leaving little time for discussion, let alone for impact assessment. But it seems plausible that exactly *because* of the time pressure, MEPs were extra keen on 'quick-fix' information, something (certain types of) IA can provide. Rapporteur Alvaro wrote in his report on the file the following:

> There was also no time for a technology assessment or for a study on the impact on the internal market. Bearing in mind the measures and plans aimed at better regulation at European level, it is to be hoped that the procedure used for debating data retention will not become the rule.[94]

Alvaro – who claimed he had to ask for the IA and only did so because it was mentioned at a Commission consultation seminar – later clarified that he found the IA on data retention *überheblich* ('presumptuous' in a rough English translation) and too much 'from the top'.[95] He expressed his surprise that no external expertise was needed, in particular because of the fact that the Commission for all its in-house expertise, does not have a high-tech internet expert. On the other hand Alvaro stated that the IA was very useful and important nonetheless 'because it states how the Commission deals with things'. The IA was only minimally discussed in the Parliament; only at the Committee level and only in the sense that a member would mention it. In Alvaro's perception the IA was rather one among many other sources of information, although it had a bit more weight as it came from an Institution. Alvaro indicated that apart from allowing an MEP to gain insight into the grounds of the Commission, an IA in his view also has an accountability function in

93 SEC(2005) 1131.
94 EP report Alvaro data retention (2005), p. 32.
95 Interview with MEP Alexander Alvaro.

the sense that it provides the possibility to say something along the lines of 'great IA, but here you did not even mention this or that'. He did 'have the feeling that if you deal with an IA as an MEP you do not really get an answer'. The IA was discussed during the 'trialogue' meetings (more informal meetings between the three co-legislators) with the Commission and the Council, but that never went further than to point out 'in your IA you say this and this, we think that and that, can you please clarify'.[96] There was no formal communication on the subject. According to Alvaro this is at least partly on the fact that procedurally speaking it is not possible for the European Parliament to ask the Commission for further work or clarifications. An additional problem that Alvaro flagged up is that the Commission officials sitting in the meetings we attend are not the same ones as those who carried out the IA. Alvaro himself did a special focus study on the effect on SMEs of implementation of the data retention. This was still at a time when specific assistance with IAs was not developed at all (apart from the framework contract that the ENVI Committee has). Alvaro stated he asked the policy department for assistance but he was told that they could not deliver, so he compiled a questionnaire together with his assistants and sent it to stakeholders.

His rather negative assessment of both the substance and the process of the data retention IA was emphasized as well in his report:

> In the interest of better regulation it is questionable whether the EU should introduce such obligations at this stage without carefully examining the long-term consequences, with a thorough impact assessment. The system of data preservation and "quick freeze" could be a better way of enhancing cooperation between industry and law enforcement agencies and ought to be analysed from a consumer and internal market point of view.[97]

Alvaro asked for his name to be withdrawn from the report after the plenary meeting in which the 'deal' with Council was confirmed and the European Parliament adopted the resolution on data retention by 378 votes in favour, 197 against and 30 abstentions.

MEP Charlotte Cederschiöld (PPE-DE), also a member of the LIBE Committee and the shadow rapporteur for the IMCO Committee in this case, also had a few encounters with IA throughout the legislative process. During the joint debate on oral questions on the transfer of passenger data MEP Cederschiöld (PPE-DE) made a link to the data retention dossier and inquired after the lack of clarity about the costs of data retention and the legitimacy of the policy:

> All day long, we have discussed the Lisbon Process and how we are to become more competitive. It cannot, then, be the right time to impose upon enterprises,

96 Interestingly, the interviewee from the Commission mentioned that the IA was not discussed at the 'trialogue meetings'.

97 EP report Alvaro data retention (2005), p. 56.

> authorities and citizens enormous costs for which we do not even have an impact assessment; in other words, costs for which there is no basis. *It seems to me entirely unreasonable and illogical to take decisions before such an assessment has been carried out* while, at the same time, discussing competitiveness and Lisbon.

Commissioner Frattini answered:

> The Commission is fully aware of the possible cost implications of data retention obligations on the providers of electronic communication services. An impact assessment will be carried out to determine to what extent the creation of obligations to retain data will have economic implications.

However the impact assessment that the Commission produced apparently failed to strike her as even worth that name. MEP Cederschiöld introduced an amendment in the LIBE committee, on having an extra IA done by an outside expert. This amendment made its way to Alvaro's report (the draft legislative resolution) in the following formulation:

> The European Parliament (…) [c]alls on the Commission, prior to the entry into force of this Directive, to commission an impact assessment study from an independent body representing all stakeholders, covering all internal market and consumer protection issues.[98]

However, as part of the big 'deal' closed by the Conference of Presidents – and by which Alvaro felt so betrayed – two demands were taken out, namely a) that this further IA should be done by an independent body and b) that this would happen before the adoption of the legislation. Carrying out an extra impact assessment would have delayed the decision-making process considerably and that was the last thing the Council (and parts of the Parliament) wanted. Without these two elements that were so crucial to Cederschiöld, a floating provision is left. The final text reads:

> The European Parliament (…) [c]alls on the Commission for an impact assessment study covering all internal market and consumer protection issues.[99]

In an interview Cederschiöld said that the Commission IA should have been done in a more qualified way and longer thinking should have gone into it.[100] More attention should have been paid to the far-reaching consequences in terms of costs and fundamental rights, not only the internal security side of it. She also pointed out that data retention is just a small little detail of a principal change that implies a move away from the traditional search for proof

98 *Ibid.*
99 EP legislative resolution data retention (2005).
100 Interview with Charlotte Cederschiöld.

to an overall surveillance and that therefore any IA should have been carried out in a wider context.

In a separate attempt to exercise control over the Commission IA, Cederschiöld posed a question to the Commission on the subject of the extended impact assessment on retention of data:

> Was the Commission's Extended Impact Assessment, SEC(2005) 1131, carried out in accordance with the Commission's own Impact Assessment Guidelines, SEC(2005) 0791?[101]

The answer from the Commission was that this was indeed the case, the impact assessment was carried out in accordance with both the 2002 and 2005 Guidelines. This answer represents the easy way out as the Guidelines contain many loopholes and few real requirements (see III.2). A more qualified answer – one that would have explained for instance in what respects the Guidelines were followed and for which issues a 'lighter touch' IA was deemed justified – would have given the Commission some credit, but it also would have created a precedent, possibly triggering more questions of this sort, something the Commission must have been keen to avoid. A more detailed formulation of IA-related questions on the part of the Parliament, clearly stating which aspects of the IA are doubted, would probably give a greater chance of success.

Council: negotiation, no integration

On an abstract level proportionality and cost were recognised as important issues by the Council and the Member States who had initiated the framework decision. However the debate failed to address these issues in an integrated way or to phrase them in terms of trade-offs. Instead the various matters to be resolved (retention period, whether authorities should only be able to request specific data or should instead be handed complete databases of existing data, the scope of the retention requirements, the boundaries set by fundamental rights) were discussed as separate items instead of any attempts of or requests for integrated cost-benefit comparison. The Commission IA was mentioned seldom during Working Party meetings.[102] One reason for this could be that Member States had the feeling that the expertise was mainly on there side anyway, with some Member States having carried out studies that the Commission build on. These include the Dutch and German studies mentioned above, but also a British study that was never published.[103]

The Council reached agreement at its meeting on 1 and 2 December 2005 with the Irish and Slovak delegations voting against. Ireland went on to file

101 Written question E-1131/06.
102 Interview national official D.
103 *Ibid.*

a case with the Court of Justice on 6 July 2006, alleging that given the subject matter the instrument should have been a Third Pillar framework decision rather than a directive. The Directive entered in force in March 2006, giving the Member States until 16 September 2007 – with a possible delay of 18 months – to transpose the requirements of the Directive into national law.[104] In many national parliaments discussions on the length of the period (the Directive prescribes a period of between six months and two years) for which they will require communications providers to retain communications data are currently ongoing. In the Netherlands the attempts to implement the Directive have encountered a negative advice from administrative burdens watchdog Actal, which found that alternatives that would be less burdensome to businesses and citizens had been insufficiently taken in to account.[105]

VII.2.5 Synthesis

Should the European Commission take IA more serious than this or is the problem rather that the IA framework becomes irrelevant if it ignores the dynamics of EU legislative decision-making (in this case the overarching political consideration that the Council had already put a proposal for a framework decision on the table)? The answer is probably: both. It is also too easy to say that this was a 'bad' IA. More usefully, it can be classified as an IA that follows the 'reason-giving' model set out in II.3.2. But although it is openly limited in its ambitions (the IA reveals its limited sources), the case also shows that there is a clear risk involved in calling such documents 'impact assessments' and using the IA template when there are no data that can carry it.

In exchange for securing the First Pillar instrument the Parliament handed the Council the substantive victory. This is quite ironic given that the motivation of the Parliament to support a First Pillar instrument was that it 'could have a say in the matter'. There was a clear appetite for IA on the part of the Parliament, but insufficient experience with handling it and, and perhaps most importantly: there was not enough time. The Parliament tried to be 'informed', but due to a below average standard of the IA as well as communication problems the IA did not play a substantial role in this process. The statement from the TEP evaluation that 'it would seem reasonable to assume that the undertaken Impact Assessment (and the analysis undertaken during this process)

104 Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC, OJ L 105, 13 April 2006, pp. 54-63.

105 Letter from Actal Chairman R.L.O. Linschoten to the Minister of Economic Affairs, No RL/PS/2007/012, 18 January 2007 (The Hague).

contributed to the relatively speedy adoption of the proposal'[106] seems wholly unfounded and is not supported by the findings set out in this chapter.

However there is one sense in which the IA did have an impact: it was one of those cases in which awareness among MEPs seemed to grow that an IA should be expected and that it is for them to scrutinise it. It is unfortunate that exactly in this case the Commission presented a 'reason-giving' type of IA, thus frustrating expectations in the Parliament to some extent. The state of affairs also fuelled criticism that the proposals that would benefit most from thorough IAs of the 'highlighting trade-off' type fail to get one, because the very political emotions IA is meant to temper end up stealing the limelight.

But impact assessment on data retention may get a second chance in the form of an ex-post assessment. As part of the legislative negotiations the Parliament secured an obligation for the Commission to 'submit an evaluation of the application of the Directive and its impact on economic operators and consumers, taking into account further developments in electronic communications technology and the statistics provided to the Commission with a view to determining whether it is necessary to amend the provisions of this Directive, in particular with regard to the list of data and the periods of retention'[107] before 15 September 2010.

VII.3 THE CASES COMPARED

These two cases have some main ingredients in common: a rapporteur who fiercely opposes the Commission proposal and tries to use IA – even taking the unusual step to engage in his own IA activities – to disqualify the Commission's reasoning. In Toubon's case it was a high-profile attempt ('the first official parliamentary IA') and in Alvaro's case it was very modest due to a lack of time and a lack of resources. But in both cases MEPs ended up feeling ignored by Commission and Council who are more interested in closing the deal already at the stage when the rapporteur tries to bring in his IA.

There are clear differences as well: in the case of pre-packaging the Commission made a real effort to go beyond producing a 'big explanatory memorandum', although the desirability of using enhanced stakeholder consultation as a substitute for impact assessment proper is doubtful as shown above. In the case of data retention the Commission consciously limited its IA to a mere justificatory document. Some would say this was inevitable with a proposal for a framework decision already on the table. But is that not what Better

106 The Evaluation Partnership (TEP) (2007).

107 Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC, OJ L 105/49, 13 April 2006, pp. 54-63.

Regulation is supposed to be all about: countering the political horse trading that is so harmful for the legitimacy of the European Union?

VIII Conclusion: the constitutional significance of IA

VIII.1 Trends from the case-studies

The case studies are mainly intended as thick accounts of possible usages and effects of IA in EU lawmaking. That is why in each of the two chapters dedicated to the four case-studies, they have been presented in narrative format with a qualitative comparison at the end. This first section of the conclusion contains an attempt to present the results from the case-studies in a more parsimonious manner. Box VIII.1 on the next page summarises the case studies, focussing on the inter-institutional dynamics. The table presented below looks at each of the three main dimensions from the case-studies and asks to what extent the impact assessments met with contestation.

Table VIII.1: Contestation in the four IA case studies

	Process contested?	*Content contested?*	*Usage contested*
REACH	Heavily	Yes	Yes
CAFE	No	No	Yes
Pack sizes	Somewhat	Somewhat	No
Data retention	Heavily	Yes	Yes

An important conclusion that can be drawn on the basis of the case studies is that process and usage tend to be more contested than the content of IA. This is surprising as many of the efforts to improve EU IA are aimed at enhancing the quality of the analysis. But the conclusion that the IA content is in fact the least contested element does not mean that these efforts should be redirected. On the contrary, it may well be that actors involved in EU lawmaking focus on the process because they are daunted by the prospect of having to engage with the actual IA results. This suggestion is in line with another finding namely that many political decision-makers do not often read the full impact assessments.[1] At best they will read the executive summary. In many cases it is more likely however that they will notice no more of the

1 The TEP external evaluation was slightly more positive, concluding that in the majority of cases under scrutiny the IA reports were read by decision-makers, although more so in the Council than in the European Parliament. The Evaluation Partnership (TEP) (2007), p. 104.

IA than a few lines in a preparatory note by their assistants or civil servants reassuring them that an IA has been done and that the proposal has been prepared in accordance with its outcome.

Box VIII.1. Concise summaries of the four IA case studies

Case study 1 'REACH' (VI.1)
A large number of impact assessments (40-50) were prepared for the high-profile revision of the EU regulatory framework for chemicals. Even the European Commission did not simply prepare one IA as is customary (and nowadays also recommended by the June 2005 Guidelines), but gave in to stakeholder pressure to revisit the original assessment. This was done through a Memorandum of Understanding concluded between the Commission and the main business stakeholders, which dictated the preconditions of the new IA to be carried out by KPMG. This course of action and a few similar episodes led to both IA content and IA process being highly contested. For some, on a positive note, the IA has achieved an enormous cost reduction. For others this case only shows that the inevitable shift towards cost-oriented considerations happens at the expense of attention for regulatory benefits. Although there are those prepared to defend that the REACH IA process reflected participatory or even deliberative ideals, for most it was mainly an example of how hard these ideals are to implement, as those stakeholders with the largest resources are seen to have the strongest voices.

Case study 2 'CAFE' (VI.2)
The joint IA for the Thematic Strategy on Air Pollution and the new Air Quality Directive was based on years of experience with assessing impacts in this policy area in various international forums and made use of very sophisticated modelling. As such, the content of the assessment went relatively uncontested, shifting all attention to the use that the European Commission made of the results. The European Commission did not choose the option that would have generated the greatest net benefits according to the IA, but chose 'second best' on the grounds that this option was more cost-effective and that IA is 'an aid not a substitute for political decision making'. The European Parliament questioned the legitimacy of this decision, asking what the point of an IA regime is, if the Commission is not prepared to let IAs be reflected in the content of its proposals, thus in effect favouring the use of hard cost-benefit analysis.

Case study 3 'pre-packaging' (VII.1)
The pre-packaging IA is part of what should have been a relatively straightforward Better Regulation file. However, for that very reason (its flavour of deregulation) this dossier was selected by the rapporteur in the European Parliament to be the first 'parliamentary IA'. The presence of contradictory impact assessments seemed to hamper inter-institutional discussion in this case rather than facilitate it. The European Parliament accused the Commission of selective consultation and of ignoring the social impacts of the proposal on weak consumers. The European Commission found the parliamentary IA utterly unconvincing and went on to propose (and secure) liberalisation of pack sizes in even more sectors than originally envisaged.

Case study 4 'data retention' (VII.2)
This IA is characterised by a lack of development of policy options and no rigorous analysis of impacts. However, in the view of the Commission this was legitimate as political events (the Council has already proposed a third pillar instrument and there was a lot of pressure to act after a new series of terrorist attacks in Europe) had forced the Commission to carry out the IA in a very late stage. Thus the IA contained little more than a justification of the Commission's choice and an overview of existing studies on the subject, reducing the IA to some sort of 'explanatory memorandum plus'. This state of affairs angered the European Parliament and stakeholders, who expected an impact assessment to contain analysis which challenges the rationality of political choices. This case provides some perspective to the oft-heard argument that even unsatisfactory IAs are a step forward as at least they provide insights into the reasoning on the part of the Commission.

The second table provides an overview of which set of assumptions of how IA should be used prevailed in each of the three co-legislating Institutions for each case-study, using the typology set out in II.3. 'Truth to power' stands for the 'speaking truth to power' model representing 'heavy' IA that not only contains full cost-benefit analysis but is also enforceable in some way (see II.3.1). 'Reason-giving' stands for the 'reason-giving for legislative decisions' model which stipulates that IA already fulfils a useful role if it explains the decision (see II.3.2). 'Stakeholder forum' stands for the 'providing a forum for stakeholder input' model that sees impact assessment as the natural ally of consultation (see II.3.3). For the 'highlighting trade-offs' model – which views ensuring political decision-makers are aware of trade-offs across impact categories and policy options as the key role of IA – and for the 'structuring the discourse' model – which sees a role for IA in enhancing the deliberative qualities of legislative decision-making – no shorter form has been used in the table.

Table VIII.2:Types of IA in the case-studies

	Commission	*EP*	*Council*	*Overall*	*Conclusion*
REACH	Mixed	Mixed	Reason-giving	Mixed	'Providing a stakeholder forum' is not proper IA. Revisiting an IA whilst raising the stakes of its results is highly problematic from a legitimacy point of view.
CAFE	Highlighting trade-offs	Truth to power	Highlighting trade-offs	Highlighting trade-offs	Expectations o f 'truth to power'are raised easily. Silent victory for 'structuring the discourse'?
Pack sizes	Structuring discourse	Highlighting trade-offs	Reason-giving	Mixed	Lack of data was filled by stakeholder input, but the IA was not used as a 'stakeholder forum' tool. After initial use of the IAs, procedural disagreement caused a return to political bargaining
Data retention	Reason-giving	Mixed	Reason-giving	Reason-giving	'Reason-giving' was often perceived as just 'bad IA'. The legislation did not gain in quality, whereas the legitimacy of IA as a tool was undermined
Overall	Mixed	Mixed	Reason-giving	Mixed	Institutions are not consistent in the way they use IA The standards to which they hold other Institutions and actors are malleable

The case studies show that IA is perceived to have different functions by different actors and by extension this holds true for different phases of the legislative process. Neither is any particular type of IA dominant within one Institution, although the Council – in line with its hyperpolitical style of decision-making – appears to have a preference for interpreting IA as a reason-giving instrument. The case studies also provide some insight into what happens if a certain type of IA is misused. The typology (see II.3) was compiled from the optimistic starting point that IA can usefully fulfil different functions, as long as the institutional structures are in place. The table below presents some suggestions as to what can happen if the various types of IAs are badly implemented, as was sometimes the case in the four dossiers scrutinised.

Table VIII.3: Types of IA with their 'worst case scenarios'

Model	*Bad implementation of model*
Speaking truth to power	Awarding unjustified weight to special interests Taking an implicit decision criterion for granted
Reason-giving for legislative decisions	Allowing decisions to be routinized Spending resources to make an explanatory memorandum look like an impact assessment without improving the quality of the legislative decision
Providing a forum for stakeholder input	Providing a forum for lobby groups with the largest resources Impact assessment becomes a tool to facilitate consultation instead of the other way around
Highlighting trade-offs	Assessing impacts without drawing consequences Substituting political decision-making after all
Structuring the discourse	Providing a forum for lobby groups with the largest resources Focussing on the procedural aspects of impact assessment and ignoring its content

REACH can be seen as a case of bad implementation of the 'stakeholder forum' model, turning IA into a forum for those with the largest resources. Of course this is only part of the story: seen as a 'reason-giving' type IA process, the Council was quite positive about the REACH IA process, convinced that it helped to bring down costs. This will hardly reassure critical stakeholders, but the only way to take EU IA successfully forward is to take the different perceptions of the IA process into account. The data retention case illuminates how hard it is to make the 'reason-giving' model work in such a way as to satisfy all actors in the process. When the institutional maturity to accept that a proposal sometimes has to be delayed in the interest of a good IA is lacking, the credibility of IA as an instrument risks being undermined. CAFE was an interesting case in illustrating how a thorough IA can raise expectations to the 'truth to power' level, even in an Institution which is normally not a fan of this model (the European Parliament). It also shows that the 'highlighting trade-offs' model may be a good one for the EU context, but that it is not unproblematic as it paradoxically shifts all attention to the decision criterion (see VIII.4.2). And yet, the inter-institutional deliberations on the terms of reference of the IA procedure may reveal the potential of the 'structuring the discourse' model for EU lawmaking (see VIII.4.3). However, the pack sizes case shows that the institutional structure for usage of IA to succeed is not yet in place, leading to frustration among those seeking to depoliticize a certain legislative proposal. The findings from the case studies also cast doubt on the validity of the idea that high quality analysis on the part of the Commission can deflect criticism from the other Institutions and stakeholders.

The main finding to be taken from the case studies can be summarised as 'process over content'. Many actors are eager to be involved in the debate on the use of impact assessments, but less keen to really engage with their content. Rather than carefully reading IA reports and using the information from impact assessments, most actors (Institutions and stakeholders alike) prefer to criticize the process.

VIII.2 CONSTITUTIONAL ASSESSMENT

What do these findings tell us about the relationship between the EU impact assessment regime and the EU constitutional framework? In the introduction it was suggested that the 'aid not substitute' conundrum was key to the influence of IA on EU lawmaking. The main distinction to look out for would be between IA as a decision-making tool (risking substitution for political decision-making) and IA as an information tool (risking being too soft). But is IA either of these two if the case studies so clearly show that the content of IA reports often does not even get a chance to be decisive or informative when the emphasis is on procedure?

With this observation in mind, the three questions relating to different roles for IA, as identified in the introduction (see I.3.2), are answered below in the light of the empirical findings of the case studies (see chapters VI and VII) and the survey of IA practice in the Institutions (see chapters III and IV) and beyond (see chapter V). However, perhaps unsurprising given the formative stage in which the EU IA regime still finds itself, none of the questions can be answered conclusively. Instead a possible agenda for further research is formulated for each question.

VIII.2.1 IA as a catalyst of legal principles

The relative lack of attention for the content of impact assessments (regardless of who the author is) does not bode well for the development of IA's capacity to function as a catalyst of legal principles. It is especially hard for both the European Parliament and the Council to integrate the IA results in the overall political discussion on Commission proposal. Too often the discussion on the IA is seen as a separate one, focussing on the question whether the IA is well-founded, rather than looking for clues in the IA document that can help with formulating a well-founded opinion on, say, the proportionality of a proposed measure. Part of this is probably due to the suspicion which still surrounds impact assessment as a new tool in EU lawmaking. It is very well possible that the introduction of the Impact Assessment Board, combined with growing experience with IA on the part of many actors will lessen the need for meta-discussions and foster a 'hands on' approach.

However, part of the reluctance to substantively engage with IA is deliberate. The state of incomplete institutionalisation is convenient for many actors as it provides them with unprecedented opportunities to impose their own preferences or values on the legislative process. The emphasis on procedure over substance means also that the emerging deference towards IA is more with respect to the *phenomenon* of IA than to individual IAs. Consequently, the norms of the IA framework could become more important than the actual results of the analyses. The case studies provide some preliminary evidence for the hypothesis that the relative immature state of institutionalisation of the tool leaves room for actors to successfully exploit the multi-interpretability of certain concepts (such as 'competitiveness') and principles (such as 'subsidiarity' or even 'maximisation of net benefits').

Can winners and losers among legal principles be identified as of yet? The main candidate for losing out is the precautionary principle. The rise to prominence of the precautionary principle is hampered by the substantive direction that Better Regulation is taking, namely a focus on cost reduction. Also, there is no evidence that the theoretical possibility identified in III.5.2 – inconclusive evidence in the IA can trigger the precautionary principle – is in fact materialising.

Subsidiarity is a different matter. Regardless of whether subsidiarity is seen as an economic principle (comparative cost-effectiveness), a legal principle, a political principle or a procedural principle, IA reports tend to contain the kind of information that is needed for a more rational consideration of the opportunity of Community action. In none of the case studies in this research project, subsidiarity was a pressing issue,[2] but the general survey of the practice shows a clear potential for strengthening subsidiarity testing through IA, with the COSAC experiments (see V.2.2) as a tangible example.

The main factor determining whether IA has a future as catalyst of legal principles will be the course of action taken by the Court of Justice. The Court has always been reluctant to enforce principles relating to the quality of legislation and has not gone beyond marginal review of Treaty requirements such as proportionality, subsidiarity and the duty to give reasons. The fact that the Commission has now spelled out in various policy documents how it thinks these norms should be operationalised has not made a difference yet. The explicit reference to IA by the Advocate General in case C-310/04, was remarkable, but perhaps not quite worth the stir it caused within the Institutions (and only there). She considered the absence of an IA to be a sign that the legislative decision may have been arbitrary, but she did not take the chance to relate this back to the norms of the IA framework. Also it should not be forgotten that, significantly or not, the Court itself did not mention

2 Perhaps it could have been an issue in the data retention dossier, but in that case many Member States were in fact pressing for legislation at the EU level. Besides, as pointed out frequently above, the IA was of the meagre, 'reason-giving' kind.

impact assessment as such. Certainly the developments in judicial review IA should be watched. However, it is not likely that the Court will use impact assessments to pin the Institutions down on particular ways of operationalising substantive principles, nor will it use IA to actively review the decision theory used by the Institutions in their lawmaking activities. That the Court will gradually hold the EU legislator to its commitment to IA as a procedural standard is more feasible. In the meantime, a fruitful research agenda could consist of carrying out medium- or large-N analyses of IA reports, to see if a certain interpretation or application of legal principles – notably subsidiarity – is dominant in the (paper) practice of IA.

VIII.2.2 IA as a constraint on the legislative process

Does impact assessment work as a fetter on legislative discretion in any way? The answer to this question hinges on the legal status of IA as much as on its practical impact on legislative processes. The legal status of IA is quickly becoming a hot topic and the literature has referred to EU Better Regulation as an instance of '*legal* borrowing' from the US.[3] Yet, it cannot be said that we are witnessing 'a 'juridification' of Europe's regulatory policies which follows grosso modo the example of the America's Administrative Procedures Act', as Joerges claims Majone's work predicts.[4] However, some limited deference from legislators and regulators towards IA – both in codecision context and beyond – is certainly developing.

The results of the survey of the general practice of IA in EU lawmaking (see chapter IV) first and foremost confirm the findings from the case studies: the use of IA varies enormously. Although actors will sometimes attempt to raise the status of the IA to that of a decision-making tool, with the aim of silencing discussions on alternative regulatory options, a survey of the practice has not seen this strategy succeeding. When IA is considered to be of bad quality, it can become a means of opposing legislation on procedural grounds. Similarly, the absence of an IA ('no IA as trump', see IV.2.4) can be used as an argument for refusing cooperation. The deference towards IA is of a limited kind only because it amounts mainly to awareness that an impact assessment has to be done in order to be able to proceed with the legislative process. It does not compel actors to abandon political stances on certain legislative issues. Nor does it extend to fostering agreement on what the legitimate course of action is in the face of a strong IA report (e.g. CAFE).

When inquiring after the potential of IA to work as a constraint on legislative discretion an important follow-up question is: 'whose discretion?'. The

3 Wiener (2006), 449 *et seq.* Emphasis AM.

4 C. Joerges, 'Der Philosoph als wahrer Rechtslehrer' (1999) 5 *European Law Journal*, 153, citing Majone (1996), pp. 291 *et seq.*

Commission has insisted that IA 'should help the Commission to exercise its right of initiative and to promote the Community method by means of fully informed political decisions'.[5] The IA procedure has been designed accordingly: it is still the Commission's prerogative to draw up the IA report and postpone its publication until the proposal is ready. However, the insistence that Commission IA serves first and foremost to facilitate internal policy preparation is fundamentally at odds with the notion of Commission IAs as starting points for legislative debates within and between all three Institutions. The case studies have shown that the information demand is of a different nature a) in different stages in the process and b) in different institutional settings (such as a parliamentary committee). This can contribute to different legislative actors having different expectations of IA when they ask themselves what the tool can do for them (see VIII.1).

The Council and the European Parliament accepted certain commitments relating to IA because, for a start, it is impossible to be *against* Better Regulation. They also hoped IA would give them more insight into the motivations of the Commission and thus provide them with a stronger basis for deciding on amendments. So far they do not seem willing to pay a price for these privileges. The Parliament is trying to fence off the side of IA that is aimed at 'disciplining the legislator', pointing to the inequality of means and expertise between itself and the Commission. The Council – with the Austrian handbook hardly implemented at all – is running out of excuses on why it is not producing IA. Yet it seems fairly content, certainly at the relatively less politicized level of Working Parties, to fit the passive use of IA (as produced by the Commission or Member States) into its routine for purposes of strategic bargaining.

Opinions are divided as to which Institution – the European Parliament or the Council – is structurally benefiting most from using IA. The answer depends on whether 'benefits' are measured in terms of performance, legitimacy or political power. Taking a bird eye's perspective, the case studies presented here show perhaps a small advantage for the Commission, as it seems that IA did help getting initiatives adopted, e.g. in the REACH case. But a note of caution when attempting to 'draw up the institutional balance' is appropriate: in 2006, when most of the interviews for this research project were carried out, there was much less awareness of impact assessment in the European Parliament and the Council than there is at present. Besides, the case studies also show some opportunities for MEPs in particular to question not just the desirability of Commission proposals but also for instance the decision criteria applied and the reasons behind the early dismissal of options. Although these opportunities were limited, some of them even outside the setting of codecision (e.g. in the CAFE case), those MEPs who have embraced impact

5 SEC(2004) 1377, p. 5.

assessment discourse, certainly made the most of them. Therefore further research should be carried out on what EU IA means for the institutional balance, with a special emphasis on the developments in the European Parliament.

VIII.2.3 IA as a space for constitutional discourse

The deadlock between the Institutions as described in the previous section (see also VIII.2.2) does not keep the debate from continuing at another level. The fact that the EU IA regime lacks symbolic value makes it an ideal vehicle for expressing constitutional differences. When the European Parliament makes a point of insisting that Commission impact assessments should be reviewed by an external body, it is really saying: 'we are the real legislator and what the Commission does is just homework'. A second example of a constitutional issue that lingers below the surface of the debate on IA concerns the constitutional role of the two advisory bodies with an explicit basis in the Treaty, the Committee of the Regions (CoR) and the European Economic and Social Committee (EESC). Both are seeking a privileged role in EU IA (see V.3) but are most of all resisting being treated as just another special interest group and seeking structural influence at the EU level as part of a broader quest for functional or territorial decentralization. The functioning of the EU IA framework as a space for constitutional discourse also means that the negotiations on its development rely on constitutional currency. Just like the European Parliament is warming up towards the idea of 'soft law' in exchange for veto power in certain comitology procedures, it is accepting that the Impact Assessment Board consists of internal reviewers in exchange for administrative burden reduction programmes.

A relevant observation in this context is also that the Better Regulation strategy received a boost, at least in terms of attention from major actors, after the failure of the constitutional project. Because of the clear governance component of Better Regulation this is perhaps not surprising. After the ratification process of the Constitutional Treaty was frozen following the negative results of the referendums in France and the Netherlands, impact assessment was rediscovered as one of the most concrete reforms that came out of the White Paper. Of course the Better Regulation strategy already was a priority before the events of May and June 2005, but back then it was still to some extent a hobby horse of some people within the Commission, notably Commissioner Verheugen, some Member States, some MEPs and many lobby groups. The difference is that afterwards a wider group of actors, previously preoccupied with the Constitution, turned towards Better Regulation, waking up to the developments that had already taken place and eager to participate in the debate. This has widened and enriched the debate, but it has also stirred up some issues that some considered either already dealt with or likely to stay

buried for a while such as administrative burden measurement and the issue of independent review. European Liberals leader Graham Watson has said about the Better Regulation strategy that:

> The battle to win back the hearts and minds of the European public [following the Dutch and French rejections of the Constitution] starts here. The Union must interfere less in those areas where it does not bring added value and focus more attention on supranational issues.[6]

There is no intention of establishing a causal link between the failure of the constitutional project and the rise of the profile of Better Regulation. In fact, it was inevitable that many of those previously indifferent to the 'bureaucratic techno-speak' that Better Regulation appeared to amount to, would wake up to the rapid changes in the lawmaking process. But it is more than likely that the desperate search for instant legitimacy boost contributed to the momentum. With the reform treaty[7] now on the table the implications of Better Regulation for the formal constitutional framework are a viable topic for future research again.

VIII.3 TWO CONTRASTING CONCEPTUALISATIONS OF IA

VIII.3.1 IA as soft constitutional law

After the analysis in the previous section of possible constitutional functions of IA, it is appropriate to have a closer look at the constitutional status of IA. It can be concluded that – for the moment at least – 'IA as a constraint' is the most salient of the three functions proposed in the introduction (I.3.2). However, clearly, EU IA does not pose a constitutional constraint in any strong sense. On the other hand, we are certainly dealing with much more than a extra-legal constraint such as 'the budget'. To do justice to its emerging status as a relevant procedural norm for EU lawmaking it is submitted that the term 'soft constitutional law' is suitable as a predicate for the IA regime. The French term for soft law, *normes douces*, expresses it even better than the English version:[8] soft

6 Http://www.euractiv.com/Article?tcmuri=tcm:29-144251-16&type=News (last accessed 15 July 2007).

7 Draft Treaty amending the Treaty on European Union and the Treaty establishing the European Community, version submitted to the Intergovernmental Conference (Foreign Ministers) meeting in Luxembourg of 15 October 2007, available at http://www.consilium.europa.eu/uedocs/cmsUpload/cg00001re01en.pdf (last accessed on 5 October 2007), Article 8c.

8 I am indebted to Eric Philippart for pointing this out to me.

law is about normativity, not about legal status. Thus the concept of 'soft law' fits well with the perspective of the constitution as 'normative environment'.[9]

The defining characteristics of soft law are that it is neither binding nor enforced. The difference with self-regulation is that the latter is often binding (through private law) but not necessarily or usually enforced through public means. Senden has compiled the following list of three core elements of soft law: 1) 'rules of conduct' or 'commitments' are concerned, which 2) are not devoid of all legal effect despite the fact that they have been laid down in instruments that have no legally binding force as such, and which 3) aim at or may lead to some practical effect or influence on behaviour.[10] Hummer mentions soft law in an article on inter-institutional agreements as 'an instrument with 'extra-legal binding effect' that raises certain expectations about the future conduct of the subjects concerned' and which 'cannot be assigned to legal categories, but [does] develop a certain binding effect and constitute 'law in the making'.[11] The European Parliament offers a different interpretation when it considers in its 2007 report on the use of 'soft law' that

> interinstitutional agreements can produce legal effects only on relationships between EU institutions and that they therefore do not constitute soft law defined in terms of a legal effect in relation to third parties.[12]

Although the Inter-Institutional Agreement on Better Lawmaking is no clear case of 'soft law', as it contains little wording aimed at binding effect (see IV.1.1), the expectations the EU IA framework (of which the IIA forms the basis) has raised among Institutions (see chapter IV) and co-actors (see chapter V) is considerable.

The important constitutional principle of 'conferred powers' stands in the way of delegating decision-making powers by other means than formal legal mechanisms. If the EU IA framework has conferred any legally relevant privileges these amount to – largely pre-existing – consultative or participatory rights. And yet, the answer to the question 'is it still possible to put forward a proposal without an IA?' is no longer an unequivocal 'yes', placing the requirement to carry out impact assessment firmly on the ladder of constitutionally relevant norms.

9 Stone Sweet (1998).
10 Senden (2004), p. 112.
11 Hummer (2007), 61.
12 EP Medina Ortega report on the use of 'soft law' (2007).

VIII.3.2 IA as a partial meta-regulatory regime

Having assessed the relationship of EU IA to the constitutional framework, it is useful to revisit the meta-regulatory perspective introduced in I.3.4. Can the EU IA regime be said to 'regulate' EU lawmaking?

Looking at the discourse used by the most unlikely proponent of anything that can impinge upon the 'dignity of legislation'[13] – the European Parliament – the answer would seem to be 'yes'. Normally weary of anything that comes close to 'new modes of governance', it seems that the Parliament has learnt how to speak the language of the regulatory state and apply it to EU lawmaking to its own advantage. The following remark by MEP Lehne is representative of the general support in the Parliament for an 'agency' for either doing or reviewing IAs:

> I have my doubts over the other existing agencies but for the first time it probably makes sense to have the kind of independent agency outside of the regular bureaucracy of the Commission doing that job of impact assessment and delivering its opinion to the Commission itself and to the law makers.[14]

However, looking at the other relevant actors the regulatory rhetoric is less strong. For impact assessment as it has developed in the EU it is still unclear who is exercising control of whom, largely because the issues of review and sanctioning are unresolved.

The two existing review bodies, the Court of Justice and the Court of Auditors have not engaged in quality control of IA or even enforcement of procedural standards for IA. However, the threat of judicial review seems to be a factor in the ongoing implementation of the IA regime, or at least this threat is being used to promote the tool. The Impact Assessment Board (IAB), an internal body established specifically for quality control purposes, has some institutional leverage, but constitutional constraints will probably keep it from taking on the task of procedural enforcement as well. Neither does this review mechanism encompass IA as a regime aimed at the whole legislative chain, being concentrated on IA as a document.

Indeed, another reason why it is unclear whether we can talk about 'meta-regulation' or 'regulation inside government' in the context of EU IA is that it is not a purely bureaucratic affair but involves political actors too. This raises the possibility that bureaucratic actors (those who effectively designed the IA system) set some of the standards for political actors (e.g. MEPs who may find themselves increasingly forced to engage with impact assessment as a prerequisite for winning an argument or proposing amendments).

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13 Waldron (1999).

14 MEP Lehne at a hearing of the Select Committee on European Union of the House of Lords, see House of Lords 9th report (2005), p. 7.

But mostly it is not clear who the regulatees are and who the regulators: the discourses in the various Institutions as well as the discourses adopted by the various 'co-actors' show that the actors involved make different assumptions about the division of tasks in EU IA. The EU IA regime also contributes to blurring the lines between the private and public spheres in EU lawmaking: lobby groups carry out IAs and demand that they are seen as equal to 'institutional' IAs and Member States sometimes see themselves as 'stakeholders', arguing for early publication of Roadmaps and IAs so that they can 'lobby' the Commission effectively.

Whereas the absence of real enforcement is a reason to qualify EU impact assessment as a partial meta-regulatory regime only, it seems that at the level of the debate on the development of the IA regime, there is too much emphasis on enforcement issues. This attention goes at the expense of attention for the fact that even 'standard-setting' is still incomplete.

VIII.4 OUTLOOK

Most actors involved in EU impact assessment are looking for legitimization, not for information. But when it comes to legitimacy there are no shortcuts, so we are back at the concept of 'informing the legislator'. This research project has shown that it is no mean feat for EU IA to provide 'a solid basis for legislative discussions',[15] but that there are enough encouraging developments to think about a way forward.

Although it has not been the main purpose of this thesis to answer the question which of the models of EU lawmaking (see II.2) is preferable, the models along with the typology of IA (see II.3) have to be revisited when faced with concrete institutional choices. The models help identify the trade-offs at the meta-level of choosing between different types of IA, ensuring the consistency of policy recommendations.

Three types of IA can be discarded, as complete and coherent models on the basis of which to make institutional choices at least. Despite the recent introduction and the relative unfamiliarity of the tool in Europe, this research has shown that there is a core of expectations surrounding IA, rendering the 'reason-giving' type of IA and the 'stakeholder forum' type incredible. As for the 'truth to power' model, apart from the fact that this rationalistic model has been frequently discredited in the literature, implementing this model will encounter constitutional obstacles. Not taking into account scenarios in which the use of IA would be abandoned altogether, this leaves three viable scenarios for the further development of the EU IA regime.

15 Lazer and Mayer-Schoenberger (1999).

VIII.4.1 Scenario 1: continuation of status quo

Impact assessment seems to have become all things to all men. A 'litmus test',[16] a 'Trojan horse',[17] a 'global standard';[18] these are all labels applied to impact assessment as it is used in EU lawmaking. The biblical phrase 'all things to all men' evokes associations with fickleness and lack of principled basis. However, upon reading the whole quotation it turns out that Paul had higher aims in mind when posing as everybody's friend, namely what political science would call 'inclusion' or 'empowerment'. The crucial element lies in the lesser known final part of the sentence:

> I have become all things to all men *so that by all possible means I might save some*.[19]

Indeed, the prevailing opinion in the EU debate seems to be that it is better to have an IA system in place than not, because of the few cases in which it will make a positive difference and that will thus be 'saved'. Inevitably the question imposes itself how far can IA go down the road of 'common sense' without losing its distinctive bite. In the face of institutional, ideological and practical objections to anything that comes close to the 'truth to power' model, it is tempting to adhere to the conviction that 'some analysis is better than none'. However if IAs which in reality contain only minimal analysis can still be used as 'shields' in the legislative process because of IA's reputation as an evidence-based tool, the bite can do real damage.

Besides, that is on a pragmatic interpretation of the phrase. Paul had an ideological purpose in mind: he became all things to all men in the name of his gospel. But the gospel of IA is not clear. Sure, it is Better Regulation, but does 'better' mean 'speedier', 'more competitive', 'more sustainable' or 'more scientific', 'more rational' or 'more governance-oriented'? Here we have reached the limits of a pluralistic approach to EU IA. For lack of a coherent aim behind EU IA, the malleability of the framework is its strength but also its weakness. When trying to move the EU regime forward in order to avoid instances of delegitimization such as in the data retention case, it is necessary

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16 J.-P. Casey, *After the Financial Services Action Plan: A Repeat of the post-1992 Blues?* (Brussels, Centre for European Policy Studies, 2005).

17 Alemanno (2007); J. Dratwa and U. Muldur, 'Analyse d'impact à la Commission Européenne: Pour quoi faire ?', *Cahier du GRASPE (Groupe de Réflexion sur l'Avenir du Service Public Européen)* (Brussels, 2006), pp. 18-20.

18 S. Jacobs, 'Current Trends in Regulatory Impact Analysis: The Challenges of Mainstreaming RIA into Policy-making', Jacobs & Associates, (Washington DC, 2006), p. 5.

19 Emphasis AM. The full citation reads: 'To those under the law I became like one under the law ... so as to win those under the law ... To those not having the law I became like one not having the law ... so as to win those not having the law. To the weak I became weak, to win the weak. I have become all things to all men so that by all possible means I might save some. I do all this for the sake of the gospel, that I may share in its blessings (1 Corinthians 9:20-23).

to think about which type of IA best fits the context of EU lawmaking. It should be remembered that no universally valid compromise between the different models is possible as each represents a coherent set of values interrelating in a certain way.[20]

But if we want to retain the current pluralism of IA types, we could think about how they fit with different types of proposals or even different regulatory sectors. One way of reducing the current air of vagueness surrounding the principle of proportionate analysis (see III.2.1) would be to specify in the Roadmap what the aims of the planned IA will be. In certain instances this could include less ambitious types such as a reason-giving IA aimed at cost reduction. Acknowledging the more limited nature of certain IAs beforehand could preempt expectations from actors that the IA will contain fully fledged analysis of all impacts. However such a practice would ask for a lot of reflexivity on the part of the European Commission and risk adding yet another layer of assessment in imposing some sort of ex ante assessment of IA. Such an extra layer has already been added with the establishment of the Impact Assessment Board, creating a new category of 'pre-legislative' documents with an unclear relationship to the final legislative decision.

VIII.4.2 Scenario 2: investing in 'highlighting trade-offs'

Assuming that we are aiming for something more than the continuation of the *status quo* one option would be to invest heavily in implementing the 'highlighting trade-offs' model (II.3.4). In this model clearly delineated policy options are the basis and therefore need to be chosen carefully. Because of the need to arrive at comparable sets of impacts for each option, they cannot change too much throughout the analysis. On top of that, the procedural rules for inter-institutional usage of IA would have to be strenghtened as the CAFE case – which roughly follows this model, see VI.2 – shows. This includes agreement on which criteria can be legitimately used to make the political decision after the IA has neatly laid out the various trade-offs: the most problematic part, as already pointed out above in VIII.1. Leaving the decision to the political level deflects from the need to include a decision criterion in the IA framework but it does not eradicate the need for a decision criterion as such.

As set out in chapter II emphasising IA's capacity to highlight trade-offs fits best with the regulatory and parliamentary models of EU lawmaking, depends on the way the IA framework would be designed. If the IA framework comes with a 'catalogue of decision criteria' this could foster a more regulatory style of lawmaking. For certain areas of law this could work well, as specific objectives have already been enshrined in the Treaty. However, it is doubtful

20 See also I.T.M. Snellen, *Boeiend en geboeid* (Alphen aan den Rijn, Samson H.D. Tjeenk Willink, 1987), p. 2.

that Member States will ever want to interpret their acts of 'delegation' to the EU level in such a strong way.

Leaving the decision criterion open fits better with the Commission's right of initiative, but contributes to the politicization of the role of the Commission. It may also contribute to parlementarization in the full sense of the word as the European Parliament will be faced with more of a real choice between policy options, a situation that approximates a parliamentary right of initiative. One side-effect of strengthening the 'highlighting trade-offs model' is that for the European Parliament it may become easier to use Commission IAs but harder to produce their own. The more extensive, more integrated kind of economic analysis that this type of IA requires may be harder to 'interrupt' for the sake of an impact assessment on substantive amendments. Finally, more emphasis on 'highlighting trade-offs' may heighten conflict in the legislative process, even in cases of 'good practice', in line with Sunstein's theory of incompletely theorized agreements. This theory claims that it is often easier for people to agree on the best solution in a concrete case than it is for them to agree on the reasons why this is the best solution.[21]

VIII.4.3 Scenario 3: a real chance for deliberation with 'structuring the discourse'?

A second possibility would be to embrace the omnipresent focus on procedural aspects and make impact assessment more of an explicit procedural tool, along the lines of the 'structuring the discourse' model (II.3.5). The pre-packaging case and the CAFE case provide some reason to believe that impact assessment can still make a valuable contribution as 'enabler of inter-institutional discussion'.

The most important difference with the implementation of the 'highlighting trade-offs' model is that for the kind of IA framework that fosters deliberative lawmaking flexibility is essential. This means much more iteration in the IA process to ensure that the policy options can be continuously adjusted in the debate, possibly even at the expense of thorough economic analysis (in view of limited resources). Impact assessment as a means of proceduralizing EU lawmaking is an attractive scenario, but it may well be too naive. Not only is there the general scepticism as to whether deliberation is a viable mode of decision-making for the EU or anywhere else, this thesis also provides some indications that IA politicizes more than it depoliticizes. If compromise is seen as essential to deliberative lawmaking,[22] IA may not be the most straightforward tool for fostering this value. Rather than enhancing flexibility in

21 Sunstein (1996).

22 See Sideri (2007) for an exploration of the notion of compromise for EU lawmaking.

regulatory options, IA seems to encourage decision-makers to become entrenched in their chosen option early on.

Paradoxically the only way to let EU IA succeed as a tool of proceduralization is to find a way to get actors focussed on the content. Deliberative lawmaking is about interaction of content and procedure and a heavy institutional framework would be needed to set this off. A necessary condition would be that the Institutions move a step closer to agreeing on common *minimum* methodologies for impact assessment. The European Parliament and the Council would also have to actively engage not just in using but also in producing impact assessment. All actors may have to accept a softer, less cost-focussed approach in order to facilitate 'IA as conversation' between political actors. A crucial issue is whether IA can provide an incentive – also for lobby groups – to report truthfully and abandon strategic argumentation. In the 'truth to power' model the solution would be found in establishing oversight agencies. But if enhancing the deliberative quality of legislative debates is the aim placing the responsibility for IA outside the political arena is not a solution. Pluralistic review by stakeholders, politicians *and* academics, of both individual IAs *and* the IA framework, taking into account content *and* procedure, is a start though.

Samenvatting

EFFECTBEOORDELING IN EU WETGEVINGSPROCESSEN

Inleiding

Constitutionele werkelijkheid omvat veel meer dan alleen de normen die zijn neergelegd in staatsrechtelijke bronnen, in het geval van de Europese Unie (EU) de Verdragen. Hoewel verschillende theoretische stromingen, zoals constitutioneel pluralisme, dit erkennen, is het idee dat we ook buiten het expliciete constitutionele discours moeten zoeken naar constitutionele normen, controversieel. Maar de aanname dat ook publieke macht net als markten 'gereguleerd' kan worden, maakt het wellicht mogelijk om een breder scala van normen en instituties herkennen die feitelijk de uitoefening van publieke macht beheersen. Zo is effectbeoordeling van regelgeving, verder aan te duiden met de ook in Nederland veel gebruikte Engelse benaming 'impact assessment' (IA), op het eerste gezicht geen onderwerp van staatsrechtelijk belang. Maar als men verder kijkt dan de oppervlakte van het discours dat impact assessment promoot als neutraal instrument ter bevordering van de concurrentiekracht en duurzaamheid in Europa, ziet men dat de recente introductie van dit wetgevingskwaliteitsgereedschap verregaande institutionele consequenties kan hebben.

Impact assessment zoals gebruikt op EU-niveau (EU IA), is het systematisch toetsen van verschillende beleidsopties op hun economische, sociale en milieugerelateerde effecten, in de allervroegste fase van beleidsontwikkeling. Daarmee gaat EU IA verder dan de verschillende Nederlandse effectentoetsen. Een belangrijk verschil zit ook in de mate van transparantie: waar Nederlandse assessments zelden hun beslag krijgen in een openbaar 'IA-rapport' met hooguit een samenvatting van de bevindingen in de Memorie van Toelichting, wordt een Europees IA-rapport meegestuurd met een wetsvoorstel en gepubliceerd op een speciale website van de Europese Commissie. Hoewel de wortels al in het Witboek over Governance uit 2001 liggen, is de IA-procedure voor het eerst uiteengezet in het Actieplan 'Vereenvoudiging en verbetering van de regelgeving' van de Commissie in 2002. Later is de procedure verder uitgewerkt in verschillende Commissiemededelingen en interne richtlijnen, alsook in het Interinstitutionele Akkoord 'Beter Wetgeven' van 2003 dat afspraken bevat over het gebruik van IA tussen de Instellingen onderling.

Deze nieuwe, geïntegreerde IA-procedure vervangt alle gedeeltelijke assessments die de Commissie in het verleden gebruikte om wetgeving van tevoren op inhoudelijke kwaliteit te beoordelen. Alleen 'ex-ante evaluatie' als zodanig, een term die door de Commissie gebruikt wordt in de beperktere betekenis van 'doorlichting op financiële en budgettaire aspecten', blijft bestaan naast de IA-procedure. Het probleem aanpakken van de vaak magere feitenbasis waarop overwegingen die tot wetgeving leiden zijn gebaseerd, is het hoofddoel. Daarmee wil men voorkomen dat wetgeving tot stand komt die slecht is voor de concurrentiekracht of de duurzaamheid van de Europese economie. Echter, impact assessment kent ook belangrijke nevendoelen gerelateerd aan het verbeteren van de kwaliteit van niet alleen de output maar ook de input van EU wetgevingsprocessen.

De veelheid van doeleinden heeft impact assessment een inherente spanning meegegeven. Deze spanning wordt in dit proefschrift belicht door verschillende interpretaties van de uitdrukking dat EU impact assessment er is om de wetgever te informeren, in kaart te brengen. De Commissie benadrukt in verschillende beleidsdocumenten dat impact assessment slechts een hulpmiddel is, bedoeld om het College van Commissarissen in staat te stellen beter geïnformeerde beslissingen te nemen en nooit ter vervanging van politieke beslissingen mag dienen. Dit uitgangspunt roept de vraag op hoe impact assessment ooit enige invloed kan hebben, als politieke overwegingen nooit hoeven te wijken.

Veel van het huidige onderzoek naar impact assessment probeert de 'impact' van het instrument zelf te evalueren door de vraag te stellen 'werkt het ja of nee?'. Ook is er veel normatieve literatuur over de wenselijkheid van impact assessment. Het uitgangspunt van dit proefschrift is dat waardevol onderzoek naar het gebruik van impact assessment de fundamentele onenigheid over de doeleinden en de randvoorwaarden dit potentieel ingrijpende instrument in aanmerking moet nemen. Een tweede uitgangspunt is dat de 'Europese wetgever' niet alleen verschillende gezichten heeft maar ook letterlijk uit verschillende Instellingen en organen bestaat.

Als we meer te weten wilen komen over hoe wetgevende beslissingen tot stand komen, moeten we niet alleen kijken naar de bevoegdheden en de politieke beinvloedingsfactoren maar ook naar de 'zachte normen' in de marge van de constitutionele besluitvorming op hoog niveau. Meta-beleid over regelgeving en IA-systemen in het bijzonder zullen invloed hebben op 'wie wat mag beslissen onder welke voorwaarden', de klassieke vraag in het staatsrecht. Ook vormen beleidsinitiatieven als 'Beter Wetgeven' de gerechtvaardigde verwachtingen van belanghebbenden (of dat nu burgers zijn of institutionele actoren) omtrent hoe wetgevende macht uitgeoefend zal worden en meer specifiek hoe beginselen van goede regelgeving in de praktijk gebracht zullen worden. Dit proefschrift heeft als doel de normatieve kracht van impact assessment bij EU wetgevingsprocessen (of het gebrek daaraan) te duiden en dat beeld af te zetten tegen het formele constitutionele kader.

De EU-wetgever informeren door middel van IA

Hervormingen van meta-beleid over regelgeving kunnen dienen als een lens waardoor problemen rondom legitimiteit en de oplossingen die een rechtssysteem daarvoor aandraagt, beter kunnen worden waargenomen. De specifieke keuzes die gemaakt worden bij wetgevingshervormingen weerspiegelen visies over de toekomst van de Europese constitutie. In hoofdstuk II worden zes wetgevingsmodellen die expliciet of impliciet worden gehanteerd in discussies over constitutionele verhoudingen onderscheiden: parlementair wetgeven, intergouvernementeel wetgeven, regulatoir wetgeven, bureaucratisch wetgeven, participatoir wetgeven en deliberatief wetgeven. Vervolgens wordt een typologie gepresenteerd van vijf verschillende manieren waarop impact assessment gebruikt kan worden in EU wetgevingsprocessen, elk verbonden met één bepaalde interpretatie van de uitdrukking 'de wetgever informeren', met bepaalde constitutionele waarden en met één of meer wetgevingsmodellen.

Model IA	*Interpretatie 'informeren'*	*Dominante waarden*	*Wetgevingsmodel*	*Relatie met constitutionele niveau*
De macht de waarheid voorhouden	Dicteren	Expertise Transparantie Verantwoording	Bureaucratisch Regulatoir	Potentieel problematisch: Daadwerkelijke zeggenschap buiten de constitutie om?
Wetgevende besluiten met redenen omkleden	Rechtvaardigen	Verantwoording Discretie	Rechterlijk Intergouvernementeel	Uitbreiding van doelstellingen Verdrag + Implementatie verplichting voorstellen met redenen te omkleden
Belanghebbenden een forum bieden	Faciliteren	Transparantie Directe democratie	Participatoir	Implementatie participatoire rechten
De aandacht vestigingen op *trade-offs*	Materieel de weg wijzen	Discretie Bewijs als basis	Regulatoir Parlementair	Kan inter-institutioneel conflict veroorzaken
Structuur geven aan het discours	Procedureel de weg wijzen	Eerlijk proces Consensus	Deliberatief	'Dichte' procedurele regels nodig (bestaan momenteel niet)

Deze modellen worden in de rest van het proefschrift gebruikt om perspectief te geven aan feitenconstellaties en om te analyseren waarom EU IA met veel meer onenigheid omgeven is dan op basis van de neutraal ogende officiële doeleinden te verwachten valt.

IA binnen de Europese Commissie

Impact assessment in de EU is begonnen als een intern instrument van de Europese Commissie. En nog steeds is de gehele IA-procedure verreweg het meest ontwikkeld binnen dit onderdeel van de Europese wetgever, dat zich laat karakteriseren door het exclusieve recht van initiatief. De grootste uitdaging voor de Commissie is het vinden van een balans tussen het behouden van politieke discretie die past bij de uitoefening van het recht van initiatief enerzijds en het verhogen van de objectiviteit van beslissingen, traditioneel het doel van IA-procedures, anderzijds.

Impact assessment door de Europese Commissie bestaat uit een aantal analytische stappen. Allereerst moet het probleem dat de grondslag vormt voor een eventuele interventie zo helder mogelijk gedefinieerd worden. De tweede stap is om de beleidsdoeleinden zo concreet mogelijk te omschrijven. Daarna zet men alle opties die deze doeleinden zouden kunnen bereiken op een rij en streept men de evident onzinnige weg. Dan volgt de impact assessment in eigenlijke zin: van al deze beleidsopties moeten de positieve en de negatieve effecten op de economie, de sociale leefomgeving en het milieu worden onderzocht en waar mogelijk worden gekwantificeerd. Ten slotte worden de opties met elkaar vergeleken in het licht van hun positieve en negatieve effecten.

De grootste institutionele innovatie binnen de fase van de IA-procedure die zich afspeelt binnen de Europese Commissie is de oprichting van een *Impact Assessment Board* (IAB) eind 2006 in antwoord op de kritiek dat impact assessments zonder externe controle nooit objectief kunnen zijn. De IAB bestaat uit vijf Directeuren-Generaal die op persoonlijke titel zijn benoemd en dus niet hun eigen Directoraat-Generaal vertegenwoordigen. Iedere impact assessment moet zes weken voor publicatie worden toegezonden aan de IAB, die zijn opinie eerste aan de desbetreffende dienst stuurt en later ook samen met het IA-rapport publiceert. Voor de ontwikkeling van het IA-normensysteem betekent dit vooral dat een interne jurisprudentie zal ontstaan over hoe de nogal losse normen uit de IA-richtlijnen geïnterpreteerd dienen te worden.

Van Commissie IA naar EU IA

In hoofdstuk IV wordt uiteengezet hoe het Europees Parlement (EP) en de Raad van Ministers als co-wetgevers a) de impact assessments van de Commissie benaderen en b) de recent aangegane verplichtingen om zelf ook impact assessments uit te voeren voor inhoudelijke amendementen op Commissievoorstellen, implementeren.

Hoewel er in het Parlement een aantal malen een poging is gedaan eigen impact assessments te produceren, is de praktijk toch nog niet echt van de grond gekomen. Veel impact assessments eindigen als 'studies' in een onopvallend gedeelte van de EP-website en hebben niet de normatieve impact die een

volwaardige impact assessment heeft. Als reden voor de trage implementatie van de verplichting uit het Interinstitutionele Akkoord 'Beter wetgeven' worden vaak praktische bezwaren aangevoerd. Echter, uit het onderzoek blijkt dat de problemen dieper gaan. Veel Europarlementariërs hebben een voorkeur voor impact assessment als procedureel argument en er zit vaak zelfs een element van sabotage bij de manier waarop men aan IA refereert in het debat. Het ontbreken van een impact assessment wordt wel aangevoerd als overweging die alle andere argumenten aftroefd. Kortom, we zien allerlei soorten gebruik, behalve de vorm die is voorzien in het Interinstitutionele Akkoord 'Beter wetgeven': daadwerkelijk gebruik van informatie, voortbouwend op de impact assessment van de Commissie.

Op het veel besproken experiment met de Batterijenrichtlijn na, ontbreekt ervaring met eigen impact assessments binnen de Raad. Net als bij het Europees Parlement is het een obstakel dat ieder criterium om vast te stellen of een impact assessment nodig is ontbreekt. Als dan ook nog institutionele prikkels en middelen ontbreken (in hogere mate nog dan in het geval van het Parlement), is het niet verbazingwekkend dat IA hooguit gebruikt wordt om bestaande politieke argumenten te onderbouwen en niet om vooronderstellingen kritisch te toetsen. Waar in de werkgroepfase nog wel enige activiteit op IA gebied kan worden waar genomen en er zelfs richtsnoeren bestaan voor werkgroepvoorzitters (vaak het 'Oostenrijkse handboek' genoemd omdat het onder Oostenrijks voorzitterschap tot stand is gekomen), lijken pogingen tot impact assessment volledig verloren te gaan zodra de besluitvorming zich naar een hoger niveau beweegt.

EU IA houdt niet op bij medebeslissing

'Er is geen bevoegdheid nodig om mee te doen', zoals een journalist van de Guardian ooit schreef over politieke weblogs. Dit gaat ook op voor impact assessment. Daarom wordt er in hoofdstuk V rekening mee gehouden dat de notie 'Europese wetgever' nog verder uitgebreid kan worden als men uitgaat van de bonte verzameling van 'co-actoren' die wellicht door de introductie van IA meer zeggenschap krijgt in het wetgevingsproces. Het ontbreken van expliciete bevoegdheden gerelateerd aan impact assessment blijkt voor de meeste actoren inderdaad geen beletsel om zich zowel in de discussie over de ontwikkeling van het IA-systeem als in de strijd om afzonderlijke impact assessments te storten. Veel co-actoren zien in het open karakter van het huidige IA-systeem een aanmoediging om door een van de ogenschijnlijk door IA omarmde waarden te benadrukken, een ingang te vinden in het beleidsproces.

Zo heeft COSAC, de Europese vereniging van EU-commissies van nationale parlementen, impact assessments gebruikt bij een experiment om nationale parlementen Europese wetsvoorstellen op subsidiariteit te laten toetsen. Het Comité van de Regio's heeft al een aantal keer het argument naar voren

gebracht dat het een actieve rol in de IA-procedure toebedeeld zou moeten krijgen en het liefst standaard betrokken zou willen worden bij opstellen van IAs. Het belangrijkste argument dat hiervoor aangevoerd wordt is dat veel effecten van Europese wetgeving op lokaal niveau gevoeld worden en er ook plaatselijke expertise nodig is om deze te meten. De Europese Rekenkamer, door een aantal auteurs gezien als mogelijke toezichthouder naar het voorbeeld van de Britse *National Audit Office*, maakt her en der referenties aan impact assessments van de Europese Commissie maar lijkt terug te schrikken van een meer structurele evaluatierol.

Ook vanuit het Hof van Justitie komen de eerste geluiden dat impact assessment een bredere en zelfs juridische relevantie kan krijgen. Er is een conclusie van Advocaat Generaal Sharpston waarin door de Commissie en de Raad aangenomen wetgeving arbitrair wordt genoemd wegen het onbreken van een impact assessment (C-310/04, Spanje/Raad). Het Hof noemt de impact assessment echter niet expliciet en leidt in plaats daarvan de vermeende verplichting een impact assessment uit te voeren af uit de omstandigheden van het geval. Bovendien wordt nergens, ook niet in de conclusie van de AG, gerefereerd aan het IA-kader. Gezien deze zeer beperkte relatie tussen impact assessment en rechterlijke toetsing is het opmerkelijk dat binnen de Europese Instellingen deze zaak is ontvangen als teken dat het Hof van Justitie bereid is de geldigheid van Europese wetgeving afhankelijk te maken van het bestaan en wellicht zelfs de inhoud van impact assessments.

Verder is de al jaren voortdurende strijd om ook comitologiebesluiten verplicht aan impact assessment te onderwerpen onlangs uitgemond in een proef met vrijwillige uitbreiding van de IA-procedure naar gedelegeerde wetgeving. Lobbygroeperingen maken al volop gebruik van de argumentatieve kracht van het instrument impact assessment, met als meest sprekende voorbeeld de groeiende praktijk om *position papers* als kant-en-klare impact assessment te presenteren.

Wetgevingscasussen I: uiteenlopend gebruik van IA in wetgeven op milieugebied

In hoofdstuk VI worden twee casussen op milieugebied vergeleken: de veelbesproken chemicaliënverordening REACH en de Thematische Strategie Luchtkwaliteit CAFE.

REACH is een uitzonderlijk geval in de zin dat meer dan 40 impact assessments zijn gedaan voor deze grootschalige herziening van de Europese chemicaliënwetgeving. Zelfs de Europese Commissie, die normaal gesproken hamert op het feit dat er slechts één geldige impact assessment is, is in dit geval terug gekomen op haar orginele impact assessment. Onder protest van vele non-governementele organisaties heeft zij een *Memorandum of Understanding* gesloten met belanghebbenden (vooral afkomstig uit het bedrijfsleven) waarin de voorwaarden voor een nieuwe IA werden neergelegd. Voor sommigen is het REACH IA-proces als geheel (dat dus meerdere afzonderlijke impact assessments

omvat) een toonbeeld van hoe het niet moet: meer en meer aandacht voor het kostenaspect van wetgeving en steeds minder voor de maatschappelijke baten. Anderen blijven erbij dat de verdienste van impact assessment in dit dossier is geweest dat het tot een aanzienlijke kostenbesparing heeft geleid in een zeer ambitieus wetgevingsproject dat lange tijd gedoemd leek te mislukken. De casus illustreert dat een participatoir gebruik van impact assessment hand in hand gaat met politisering van het proces.

De CAFE-casus speelde zich af in een heel andere context: de impact assessment kon voortbouwen op jarenlange ervaring met modellering van effecten in verschillende internationale fora. Wat deze casus echter goed laat zien is dat een weinig controversiële gang van zaken bij de totstandkoming van een impact assessment (procedure en inhoud) geen garantie is voor harmonieus gebruik ervan. De Europese Commissie kreeg zware kritiek te verduren vanuit het Europees Parlement omdat zij niet de beleidsoptie met de hoogste baten had gekozen, maar de 'op één na beste' optie. Volgens het Parlement was dit het bewijs dat de Europese Commissie niet bereid is consequenties te trekken uit het nieuwe IA-systeem. Het standpunt van de Commissie is dat CAFE een voorbeeld is van volledig legitiem gebruik van impact assessment, aangezien kosteneffectiviteit ook een belangrijke overweging is en impact assessment bovendien ondergeschikt is aan politieke besluitvorming. Deze discussie laat zien dat de Instellingen opportunistisch zijn bij het steunen van bepaalde typen gebruik van IA en dat de normen waar zij andere Instellingen en actoren aan willen houden verschillen van de normen die zij zelf in de praktijk brengen. De casus toont ook aan hoe het goed mogelijk is om impact assessments te gebruiken om *trade-offs* te illustreren, maar dat dit type gebruik ook de aandacht verschuift naar het beslissingscriterium dat de wetgever hanteert. Het debat ging uiteindelijk over de vraag 'waarom nemen we nu eigenlijk juist dit besluit?' en dat is hoopgevend voor de levensvatbaarheid van het deliberatieve model.

Wetgevingscasussen II: pleiten voor actie op EU-niveau: marktliberalisering and JVV

In hoofdstuk VII wordt de beruchte dataretentierichtlijn tegenover de nieuwe wetgeving over verpakkingsgroottes gezet. Deze dossiers hebben gemeen dat zowel op het gebied van marktliberalisering (verpakkingsgroottes) als op het terrein van justitie, vrijheid en veiligheid (dataretentie) de Europese Commissie extra moeite moet doen om hard te maken dat ingrijpen door de EU nodig is.

Het verpakkingsdossier is een kleine mijlpaal voor EU impact assessment, omdat het de eerste wetgevingsprocedure is waarin het Europees Parlement officieel een impact assessment heeft uitgevoerd. Maar omdat het Parlement en de Commissie veel kritiek hadden op elkaars methodologie, kwam men niet toe aan een discussie over de reguleringsproblematiek op basis van de inhoud van de impact assessments.

De impact assessment van de Europese Commissie in het dataretentiedossier heeft veel kritiek gekregen, zowel van het Europees Parlement als van een aantal non-gouvernementele organisaties. Zoals, gezien de politieke hectiek waarmee dit voorstel omgeven was wellicht te verwachten viel, worden alternatieven voor de voorgestelde richtlijn niet serieus besproken en ontbreekt een rigoreuze analyse van de effecten. De impact assessment leest als een overzicht van argumenten en voorgaande studies. Men kan zich op het standpunt stellen dat een impact assessment als deze nog steeds een nuttige functie kan vervullen als een soort uitgebreide Memorie van Toelichting. Echter, een analyse van het debat over dit voorstel laat zien dat het label 'impact assessment' bepaalde verwachtingen wekt omtrent de kwaliteit van de analyse die wordt gepresenteerd en dat een 'redengevende' impact assessment de legitimiteit van het instrument als zodanig kan ondermijnen.

Conclusie: het constitutionele belang van IA

De conclusie haalt allereerst een paar algemene lijnen uit de case studies naar voren. Ten eerste is opvallend dat de manier waarop de wetgevingsactoren gebruik maken van impact assessments over het algemeen meer wordt betwist dan de inhoud van het IA-rapport of de IA-procedure. Dit kan echter goed komen doordat de ingewikkeldheid van de informatie afschrikt. Kwaliteit van de analyse lijkt niet gcorreleerd te zijn met de mate van kritiek op een Commissievoorstel. Een nogal banale – hieraan gerelateerde – vondst van de empirische component van het onderzoek is dat impact assessments nauwelijks gelezen worden, ook niet door degenen die er later wel een mening over ventileren.

Het onderzoekskader ging uit van een onderscheid tussen impact assessment als besluitvormingsinstrument en als informatieinstrument. Naar aanleiding van het empirisch onderzoek dient de vraag zich aan of EU IA wel een van beide is. Over het algemeen is de discussie over de IA weinig geïntegreerd met het debat over het voorstel als zodanig omdat men liever de aandacht vestigt op de procedurele aspecten van IA. Het fenomeen impact assessment geniet meer ontzag dan de daadwerkelijke impact assessments. Impact assessment faciliteert ook geen snelle overeenkomst tussen de verschillende onderdelen van de wetgever.

Hoewel het bij deze stand van zaken onmogelijk is de constitutionele betekenis van impact assessment exact te duiden, is het antwoord op de vraag 'mag een wetsvoorstel worden ingediend zonder impact assessment?' geen ondubbelzinning 'nee' meer. Impact assessment fungeert als een 'zachte' constitutionele norm en kan ook gezien worden als een incomplete vorm van meta-regulering. In het debat over EU IA en in het bijzonder in de discussie over de noodzaak van een (externe) toezichthouder, wekken actoren de indruk uit te zijn op het reguleren van het Europese wetgevingsproces.

Zonder uitspraak te doen over welk wetgevingsmodel in zijn algemeenheid het best is, komen uit de de chaos van verschillende assessmentmodellen twee

soorten gebruik van IA naar voren als het meest coherent en geloofwaardig: 'de aandacht vestigingen op trade-offs' en 'structuur geven aan het discours'.

Wat brengt de toekomst? Een pluralistische voortzetting van de status quo is een realistische mogelijkheid. In dat geval zouden de verwachtingen van belanghebbenden echter wel bijgesteld moeten worden. Eén gedachte zou zijn om bij een verder uitwerking van het beginsel van evenredige analyse, te specificeren welk type IA het meest geschikt is voor welke wetgevingssituatie. Investeren in het belichten van *trade-offs* is een tweede mogelijkheid, een die wel ten koste gaat van de flexibiliteit van het instrument aangezien de opties al in een vroeg stadium vastgesteld moeten worden om goed vergeleken te kunnen worden. Kiezen voor een meer deliberatief gebruik – het derde scenario – houdt juist in dat de economische analyse minder grondig zal kunnen zijn omdat er meerdere malen op eerder gemaakte keuzes moet kunnen worden teruggekomen.

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Appendix: list of interviewees

This list includes all formal interviews conducted for the purpose of this thesis.

Council of Ministers (national officials attending Working Parties):
National official A, 2 June 2006
National official B, 1 June 2006
National official C, 2 October 2006
National official D, 9 November 2006

European Commission:
Commission official A, 19 June 2007
Commission official C, 9 February 2007
Commission official D, 1 June 2006

European Parliament:
MEP Alexander Alvaro (phone interview), 2 June 2006
MEP Charlotte Cederschiöld, 30 May 2006
MEP Dorette Corbey (phone interview), 29 September 2006
MEP Jacques Toubon, 1 June 2006
Assistant to MEP Caroline Jackson, 8 February 2007

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Curriculum vitae

Anne Claartje Margreet Meuwese werd op 16 juni 1980 geboren te Nijmegen. In juni 1996 behaalde zij haar eindexamen aan het Stedelijk Gymnasium Nijmegen. In het academisch jaar 1996-1997 bezocht zij de Horikawa High-school in Kyoto, in het kader van een Rotary-jeugduitwisseling naar Japan. Van 1997 tot 2002 studeerde Anne Nederlands recht aan de Universiteit Leiden, waar zij cum laude afstudeerde met als afstudeerspecialisatie staats- en bestuursrecht. Tijdens haar rechtenstudie studeerde Anne gedurende één semester aan Sciences-Po in Parijs. In 2002-2003 studeerde zij aan de University of Oxford (Balliol College). Hier volgde zij vakken op het gebied van vergelijkend en Engels publiekrecht, rechtsfilosofie & politieke theorie en reguleringsvraagstukken en heeft zij de graad van Magister Juris (M.Jur.) heeft behaald. In september 2003 kwam Anne terug naar Leiden om in dienst te treden als PhD-fellow bij de Afdeling Staats- en Bestuursrecht. In de zomer van 2004 nam zij deel aan de summer school van de Academy of European Law van het EUI in Florence en behaalde zij het diploma. Van maart tot en met juli 2005 liep zij stage bij de afdeling 'Better Regulation and Institutional Matters' van het Secretariaat-Generaal van de Europese Commissie in Brussels. Sinds maart 2006 werkt Anne als onderzoeker bij de afdeling Politicologie (Centre for Regulatory Governance) van de University of Exeter. Ook is zij nog als gastmedewerker verbonden aan de afdeling Staats- en Bestuursrecht van de Leidse rechtenfaculteit.

Anne Claartje Margreet Meuwese was born on 16 June 1980 in Nijmegen, the Netherlands. She received her secondary school diploma from the Stedelijk Gymnasium Nijmegen in June 1996. In the academic year 1996-1997 she attended Horikawa Highschool in Kyoto, as part of a Rotary Youth Exchange to Japan. From 1997 to 2002 Anne studied Dutch Law at Leiden University, from which she graduated with distinction, having specialised in constitutional and administrative law. During her undergraduate studies in law Anne spent one semester at Sciences-Po in Paris. In 2002-2003 she studied at the University of Oxford (Balliol College). She completed courses on comparative and English public law, jurisprudence & political theory and regulation and was awarded the Magister Juris (M.Jur.) degree. In September 2003 Anne returned to Leiden to work as a junior teaching fellow/researcher in Constitutional and Administrative Law. In 2004 she participated in the summer school of the Academy

of European Law of the EUI in Florence and obtained its diploma. Between March and July 2005 Anne was a trainee at the unit 'Better Regulation and Institutional Matters' of the European Commission's Secretariat-General in Brussels. From March 2006 onwards Anne is a research fellow at the Politics Department (Centre for Regulatory Governance) of the University of Exeter. She remains affiliated with the Leiden Law Faculty through a non-stipendiary fellowship at the department of Constitutional and Administrative Law.

In de boekenreeks van het E.M. Meijers Instituut voor Rechtswetenschappelijk Onderzoek van de Faculteit der Rechtsgeleerdheid, Universiteit Leiden, zijn in 2006 en 2007 verschenen:

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