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How the regulatory state differs The constitutional dimensions of rulemaking in the European Union and the United States

by Claudio M. Radaelli and Anne C.M. Meuwese

1. Introduction: federalism, constitutionalism and the regulatory state

With the entry into force of the Lisbon Treaty and the changes under way in the economic governance of Europe, most of the attention is rightly focused on the constitutional, and, perhaps, federalizing elements of the European Union (EU), in comparison to the type of constitutional politics and federalist structures that have molded political development in America (Nicolaidis and Howse 2001; Menon and Schain 2006; Fabbrini 2010). This renewed constitutional debate ties in with the literature on comparative federalism. It is common to observe that some features of the American political system, for a long time considered exceptional, have migrated to the European Union (Majone 1996). According to this strand of scholarship, both the federal government in the USA and the European Union (EU) institutions have developed their core functions around regulation rather than public expenditure and taxation. This makes them structurally similar and different from the type of welfare state that emerged in the Bismarckian and Scandinavian states of Europe. However, this similarity in broad design principles does not mean that the EU and the USA have adjusted these principles to the constitution in a similar way.

We contribute to this lively comparative discussion of the connections between constitutionalism and regulation in two ways. First, we add to the

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comparison of the federal features of the EU and the USA by focusing on EU day-to-day constitutional dynamics that have been overlooked, perhaps because of their subtle, low-politics, less visible implications and their «insignificance» when compared to treaty revisions. Interestingly, we observe that many of these apparently insignificant constitutional changes under way have their roots in regulatory procedures. It is puzzling that whilst hundreds of conferences were debating the likely constitutional effects of the Treaty on the Functioning of the European Union (TFEU), a quiet constitutional change has been under way for almost a decade, with the emergence of the «better regulation» or «smart regulation» agenda – a phenomenon structurally similar to the growth of regulatory oversight in the USA. We argue that there are important constitutional lessons to draw about this quiet revolution.

Second, within the field of regulatory politics, we focus on a wave of reforms identified by concepts such as «better regulation» – this is the term often used in the EU, together with «smart regulation» (European Commission 2010) – and, in Washington, «regulatory oversight». This is a family of initiatives affecting rulemaking. It includes mandatory consultation, obligations to publish regulatory proposals for notice and comment, plans to reduce administrative obligations, the economic analysis of proposed regulation, as well as the creation of special-purpose oversight bodies such as the Impact Assessment Board in the EU and the Office for Information and Regulatory Affairs within the Office for Management and Budget in the USA.

More often than not, we will draw attention to an important tool of smart regulation, i.e., impact assessment (IA as it is known in the EU or «regulatory impact assessment», RIA in the USA)¹. Impact assessment is a mandatory administrative procedure (Renda 2006; Wiener 2006; Hahn and Tetlock 2008; Radaelli and De Francesco 2010). Its thrust is to subject proposals for new rules to a process of consultation, evidence-based debate, identification of costs and benefits (often but not exclusively via cost-benefit analysis principles), risks, and socio-economic effects in general, possibly in relation to a wide range of stakeholders and the environment. Impact assessment as concept covers both the *process* and the *document* prepared by the regulator and scrutinized by a regulatory oversight body before new rules enter the Federal Register in the USA or are sent as draft legislation to the European Parliament and the Council in the EU. Increasingly the EU version of the impact assessment procedure covers delegated and implementing measures too. By institutionalizing participatory procedures and economic tests (or a

¹Throughout the paper will we use the term RIA to describe both the European and American experience. It will become clear, however, that RIA is used for rulemaking in the USA and for legislative proposals in the EU – the usage of impact appraisal procedures for rulemaking («comitology») is limited in the EU.

mixture of those), regulatory oversight and «better regulation» potentially intervene on the traditional democratic deficit that supranational and even federalist regulatory regimes suffer from. In this way tools like RIA directly touch upon the big constitutional question: who gets to decide what, and under which conditions?

In this article we explain the institutionalization of smart regulation and explore its constitutional implications, bearing in mind the fact that the American example has a much longer history. We also stress that we focus on the EU case, using the experience in the USA as contrast case. In the next Section we present our conceptual framework, based on socio-legal studies and positive political economy. We then present our findings on institutionalization in Section 3, whilst Section 4 is dedicated to the constitutional implications. Section 5 briefly concludes with an assessment of the implications of our findings for comparative regulatory federalism and the regulatory state in Europe.

Constitution, regulation, regulatory constitutionalism, and the politics of structure

At the outset, we need to clarify what we mean by *constitution*. For our purposes, we need to adopt Neil Walker's (2002) pluralist concept of constitution, widely shared among socio-legal scholars, which entails that constitutional politics encompasses a broad range of political relations between the institutions of the political system. This notion enables us to go beyond the American Constitution and the Treaties of the European Union. It allows us to also consider that constitutional politics is dynamic, based on real-world changing power relations. An important implication is that constitutional relations change when new procedures or simply ways of doing things alter the balance of power between an institution and the others.

We can now enter our second key-term, that is, *regulation*. Rulemaking requirements affect among other things the delicate stage of pre-legislative scrutiny of policy proposals. These requirements can be manipulated by the President of the USA to limit agencies, or by the agencies to create constituencies of support vis-à-vis the Office for Management and Budget and get away with more regulatory proposals. They can be used by the European Commission to make its proposals to the European Parliament and Council less easy to change, or by the Member States and the pressure groups to challenge the bureaucracy when proposals are formulated. All these are changes of constitutional relevance.

Having defined the conceptual dimensions of constitutionalism and regulation, we have to connect the two. This is not an easy task. But during the last decade, a body of socio-legal literature, often blended with political

science, has made an effort to come to grips with the notion of regulatory constitutionalism (Morgan 2003; Scott 2004; Prosser 2010; Oliver et al. 2010). Colin Scott has put forward an approach to constitutionalism intimately connected to how political scientists, and particularly among them delegation theorists, think of regulatory policy. Granted that constitutionalism is «the commitment to effectively limit the exercise of legislative and executive power» (Scott 2010, 17), when executive and legislative power are delegated, there is a need to create similar controls and limits. Since regulatory power is delegation politics, «from the perspective of constitutionalism, delegation is the central problem associated with contemporary regulatory governance» (Thatcher and Stone-Sweet 2002; Scott 2010, 17). The constitutional effects of this commitment to impose requirements on delegated regulatory power emerge with the routinization of mechanisms for the «promulgation of new regulatory rules». These mechanisms have the «potential to fundamentally affect the stock of constitutional controls over the exercise of power» (Scott 2010, 24). «Accordingly» – he goes on – «one way to approach the potential for reconciling regulatory governance with constitutionalism is to identify examples where institutionalized solutions have been developed» (Scott 2010, 25). RIA is a case in point.

To exemplify then, in her study of regulatory reform in Australia, Morgan argues that cost-benefit analysis (CBA), incorporated in requirements for impact assessment, institutionalizes «a presumption in favor of market governance, and this causes bureaucrats to reform or 'translate' aspects of social welfare that previously may have been expressed in the language of need, vulnerability or harm into the language of market failures or market distortion» (Morgan 2003, 491). Looking at the UK, Prosser (2010) finds instead that the regulatory enterprise is certainly concerned with economic efficiency, but nowadays regulators are also compelled to respect human rights (a trend that emerged in the US in the 1970s), solidarity, and sustainability. It is not just a matter of values. The new powers given across Europe to ministers to lift burdens and re-organize regulators have re-shaped relations between the core executive and the other major constitutional players. Julia Black (2007) has thus evidenced the centralizing effects of new regulatory reforms in the UK.

Let us re-cap and move forward with our conceptual framework. Regulatory constitutionalism concerns the limitation of power arising out of problems of delegation and collective action. The constitution is not only a set of text, but a set of political dynamics. When regulatory mechanisms alter the political power between an institution and the others, they have constitutional effects. These effects – we add – cannot be predicted by looking at the design characteristics of regulatory oversight and rulemaking requirements. They depend on how they occur empirically, over a sufficiently long period

of time. «Fundamental» rulemaking obligations may become perfunctory. «Details» can be implemented rigorously instead.

To complete our understanding of regulatory constitutionalism from an empirical perspective, we need the notion of politics of structure put forward by Terry Moe in several publications (e.g. Moe 1989; Moe and Wilson 1994). Moe introduced a major difference between the design of policy and the design of structure. Policy revolves around concrete issues, such as housing, transport, and the environment. The politics of structure is about the design of certain procedures that shape the interaction between Congress and President (specifically «their capacities for exercising power»), and between bureaucracies and elected politicians (a «struggle» involving «the institutions that will interpret, elaborate and carry out public policy: the bureaucracy»). The two dimensions of the politics of structure are connected, since «the struggle between the President and the Congress [...] while often manifested in wellpublicized battles over policy, is largely a structural matter. It is a matter of how each institution can engineer the structure of public bureaucracy and exercise control over it» (all quotes from Moe and Wilson 1994: 4). In contrast to policy issues, structural issues are regarded as «boring, arcane, impossible to understand, and irrelevant to politics» (Moe and Wilson 1994, 5).

Yet these apparently insignificant issues of structure determine institutional power. One of the three case studies used by Moe and Wilson to illustrate structural politics is indeed concerned with RIA since, they argue, this is the procedure that stacks the deck in the relationship between principal and agent (McCubbins *et al.* 1987). Requirements such as RIA and costbenefit analysis do not (only) exist to deliver efficiency gains, but to tilt the relationship between elected politicians and regulatory officers (Pildes and Sunstein 1995; Posner 2001) and between Presidents and Congress (Moe and Wilson,1994, 42).

Before we enter our empirical analysis, a word of caution is in order. We do not argue that the changes triggered by the better regulation agenda are more important than the high constitutional politics issues that have dominated the discussion since the White Paper on Governance launched by the Commission in 2001 (European Commission 2001). Rather, we make the point that – no matter what their relationship with treaty-based changes is – they belong to the changing puzzle of constitutional change that has polarized the attention of the participants to the grand debate. But they deserve to be examined and explained on their own merits, since they are not the product of inter-governmental conferences and treaty revisions. The first step is to explain how they emerged and were institutionalized, taking into account the longer time period for the development of regulatory oversight in the USA and the shorter history of better regulation in the EU (Wiener 2006).

3. Research design

To use this conceptual framework for comparative analysis, we have to generate suitable questions for the analysis of the quiet constitutional change triggered by procedures affecting rulemaking.

We consider the changes affecting rulemaking (i.e., smart regulation initiatives) in two modes: as dependent variable and independent variable. Put differently, we follow two itineraries: from constitutional problems of delegation to regulation; and from regulation to constitutional effects. This way we can appraise the full circle of regulatory constitutionalism.

Concerning the sequence from constitutional politics to regulation, the research question is about processes of institutionalization: what are the mechanisms that have led from problems of constitutional politics (arising out of delegation) to the institutionalization of smart regulation in the two systems? Here smart regulation is therefore a dependent variable, and we look at the causes of an effect (that is, institutionalization). As for the conceptual journey from regulation to constitutional politics, the question is: what are the constitutional effects of this institutionalization? We will consider four types of effects: (a) on constitutional values, (b) on the relations between the core legislative institutions, (c) on the position of the executive and (d) on accountability. Here smart regulation is the independent variable, and we look at the effects of a cause.

We collected empirical material on both the EU and the USA. However, our original evidence (case studies, interviews, coding of impact assessments) is almost entirely based on the EU, with the exception of a dozen of semi-structured interviews carried out in Washington. Thus, in terms of the specific choice of a comparative technique, this article is based on the EU case, contrasted for comparative purposes with the American case. This has implications for the level of detail we can use when we describe the American case. For instance, some readers may disagree with our characterization of the American executive as unitary, but this discussion is beyond the scope of this article (see Blumstein 2001; Kagan 2001; West 2006; Fabbrini 2010). In short, we think comparatively but this is not an explicit comparison of empirical evidence gathered evenly on two cases. Since we have research questions covering different and relatively long periods of time (since 1981 in the USA; since 2003 in the EU), it is impossible to go to the level of detail of describing individual episodes of rulemaking – such as individual impact assessments. The analysis will therefore be carried out at a macro-level, with individual regulations mentioned only as examples. For comparisons of relatively large numbers of RIAs across different political systems see Cecot et al. (2008) and Fritsch et al. (2012).

4. From constitutional politics to regulation

In this section we compare the evolution of the requirement to carry out economic analysis of proposed regulation, a requirement that both in the USA and the EU also implies obligations of transparency, consultation, and access to documentation. How did the initial steps to tighten control on regulatory bureaucracies get embedded in the rulemaking process? The explanation of institutionalization outcomes is fundamental to understand the broader constitutional politics that originates changes – according to Moe, this is how we shed light on the power dimension of who gets what in creating institutions (Moe 2005).

As mentioned, in the USA the notion of smart regulation is less popular and more recent than the concept of regulatory oversight (Hahn and Tetlock 2008). This focus on oversight reminds us that in Washington the evolution of administrative procedures such as impact assessment, cost-benefit analysis, consultation, and giving reasons obligations arose out of problems of delegation and oversight already partially addressed in the Administrative Procedure Act of 1946. In the course of the political development of the American federal executive, regulatory power was delegated to federal executive agencies of the Presidential administration, such as the Environmental Protection Agency and the Occupational Safety and Health Administration. Federal executive agencies belong to the Presidential administration and together with other Presidential offices constitute the unitary executive (Blumstein 2001).

There are consequences for the logic of delegation. In the case of federal executive agencies, delegation seeks to keep the preferences of the agencies in line with the Presidential preferences within a unitary executive and direct oversight from the Office for Management and Budget (OMB). In the case of independent agencies, delegation is based on the assumption that agencies have preferences that differ from the preferences of elected politicians. This is because the act of delegation is informed by a logic of credibility of independent regulators – and credibility is higher if the agency is not subject to the vagaries of the election cycle (Majone 2001).

The constitutional delimitation of Presidential control is therefore tight. Impact assessment procedures are an efficient control device in these circumstances. Consider the following options. The President as principal can limit the autonomy of federal executive agencies ex-ante (e.g., federal executive agencies can be saddled with political appointees) or ex-post (e.g., budget restrictions for agencies that do not follow the line of the White House or Congress). But these approaches are quite blunt and do not operate on a case-by-case basis, when single rules are being formulated. When individual regulations are made, agencies enjoy the privilege of information asymmetry,

since they have much more information on the regulated entities and the possible effects of regulations than the President (de facto represented by the Office for Information and Regulatory Affairs within the OMB). To limit the possibility that agencies in the federal Presidential administration exploit this asymmetry, the principal imposes an administrative requirement to publish for notice and comment an economic analysis of how the regulatees will be affected by the proposed rule. This provides information to pressure groups that feel damaged by agencies deviating from the preference of the President, represented in this process by the OMB. RIA is an administrative requirement that performs this function of controlling regulatory bureaucracies when they produce regulation. In contrast to control tools that operate either before or after rulemaking, RIA is an ongoing control device.

The American RIA has emerged from the Administrative Procedure Act's general rulemaking obligations via a series of executive orders, commencing with Reagan's order no. 12291. It has been used by all Presidents – no President has ever decided not to use it. As such, it has emerged as a relatively bipartisan enterprise – with some variations in terms of transparency requirements and inclusiveness of the cost-benefit analysis (Kagan 2001). This has produced the effect – in terms of Moe's structural politics – of deepening the control function of this policy instrument (the RIA) on agencies and integrating federal executive agencies more closely into the Presidential administration. This bipartisan line is evidence that the essence of the instrument is structural: it is indeed about the control of the bureaucracy rather than specific policy goals.

Apart from Presidents, the second source of institutionalization has come from judicial review by the courts, with a series of landmark judgments on the principles of risk regulation and cost-benefit analysis in federal executive agencies (Majone 2010). Taken together, courts and Presidents have drawn over the years a structural map of what oversight is supposed to do. Independently of fluctuations of regulatory policy preferences across administrations, the notion of controlling the bureaucracy has remained unchallenged.

Constitutionally, the legitimacy of control exercised by the President has been anchored to the fact that the imposition of RIA requirements covers only federal executive agencies. Agencies that fall outside the Presidential administration, such as the independent regulatory agencies active at the federal level, up until now have not been covered by the executive orders on the economic analysis of regulation. Further, primary legislation is not subjected to RIA – the justification is that Congress has enough tools (committee work, hearings and so on) to make informed decisions about legislation. Thus, the institutional territory of RIA is limited. Although there is an on-going discussion on whether RIA-type requirements should go beyond this territory, for the time being there has not been any notable change.

Turning to the EU, smart regulation has emerged in a different context. To begin with, there are obvious differences regarding the «principal» – given the fusion of powers that characterizes the EU polity – a mixed polity according to Majone (2005). In Brussels, it is difficult to find the equivalent of the unitary executive described by Blumstein and other American lawyers. True, there is an EU executive function, but it does not crystallize around the figure of the President of the Commission. Neither can the Commission as a whole be described as the executive of the EU, although it certainly has some executive functions.

Second, in Europe judicial review of regulations follows a peculiar dynamic: the Court of Justice only marginally reviews for certain principles such as subsidiarity and is known to be stricter (e.g. in its application of the proportionality principle) on Member State rules deemed contrary to EU law than on EU-level rules (Craig 2006). Hence, in the process of institutionalizing RIA and the gradual specification of cost-benefit analysis principles courts are currently present only in the background (Alemanno 2009). A few qualifications have to be made here though. There is evidence that certain design choices for the RIA system by the Commission have been made taking into account the «risk» of judicial review. For instance, although the Commission is known to use RIA to rally support for its proposals, it stresses the internal nature of RIA documents over and over again in official communications. Also, the situation that European citizens still do not have standing in front of the Court of Justice to appeal against general rules is showing the first signs of shifting in the future, since the Treaty of Lisbon gives individuals standing to appeal EU regulations that are directly applicable without implementing measures (art. 263 TFEU). Finally, the European Court of Justice might indirectly look at impact assessment in reviewing EU decisions as supporting evidence of the way in which the Commission exercised its discretion (Alemanno 2009). But up until now the situation has been quite different on the two sides of the Atlantic.

Third, whilst in the USA regulatory oversight has been grounded in the Administrative Procedure Act (APA) of 1946, the debate on a possible APA for Europe is still open (Meuwese *et al.* 2009). This means that the old EU constitutional bargain of leaving it to a central bureaucracy (the Commission) to make regulatory trade-offs in the «common interest» remains intact.

Fourth, the enthusiasm for «rational» policy analysis, quantitative risk assessment and cost-benefit analysis is more limited in Europe (Wiener 2006). If anything, the Commission has instead opted for a range of regulatory decision-making principles, without endorsing cost-benefit analysis as necessarily preferable to others. Given this European «regulatory philosophy», it is not surprising that the EU RIA system operates with a preference for pluralistic methods, or, better, a tendency to complement «cost-benefit thinking» with

other decision criteria such as «coherence» or even «compatibility with the internal market» and «fundamental rights protection».

All this considered, how do we explain institutionalization in the EU? Two variables explain the outcome. One has something to do with the politics of delegation – in the context of institutional balance and the right of initiative of the Commission; the other with infra-organizational politics and learning in the Commission. Let us start with delegation.

Absent the Presidential control of regulatory agencies, an EU-level functional equivalent of the politics of delegation we have seen at work in the USA is the relationship between Member States and the European Parliament, on the one hand, and the Commission, on the other. Acting as principal, since 1992 the Member States, or at least some of the most active among them, have pressed the Commission for procedural innovations on the quality and quantity of legislation. The European Parliament, a relatively young institution when compared to Congress, has seized the opportunity to re-define its position in the lawmaking process by adding to the changes already brought about by the Treaties since the 1980s a plea for «better legislation» – effectively asking for new requirements restricting the right to initiate legislation of the European Commission.

This has led to some changes at the macro level, with inter-institutional agreements on the quality of legislation, Council declarations and protocols annexed to the treaties. The Commission has reported annually on the application of the principles of subsidiarity and proportionality – gradually extended to Better Regulation more generally – ever since the Edinburgh Council Conclusions in 1992, an obligation that was formalized 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.

But the real battle was fought at the micro-level of everyday politics and annual strategies on «better legislation» in the 1990s – soon to become «better regulation» in the next decade. At the micro level, the Commission experimented in the 1990s with several prototypes of better regulation tools, such as business impact appraisal systems, guidelines on drafting, different approaches to consultation, and simplification of single market rules. The call for less and better legislation from Brussels was also connected to the constitutional problems of legitimacy, accountability and credibility of Community regulation – problems that became acute in the second half of the 1990s. The White Paper of the Commission on governance (European Commission 2001) contemplated a whole set of initiatives to address these problems – with better regulation tools in pole position. In 2002 the Commission adopted the first comprehensive better regulation plan and an integrated RIA. With modifications, the notion of appraising policy proposals via RIA

has remained at the core of the Commission strategy, together with initiatives to reduce administrative burdens at the EU level.

With RIA, the «principal», in our case the Member States, seeks to force the Commission to early forms of open and systematic consultation, use of empirical evidence, and publication of the analysis at the time a proposal is agreed upon by the College of Commissioners. In turn, the RIA report is much more analytical than the classic explanatory memoranda, being based on the economic analysis of various effects of proposed regulation on different categories of stakeholders. The preparation of the major RIAs is an opportunity for domestic industry and pressure groups to expose the particular categories and magnitude of costs arising out of different regulatory options – in principle, a good way for governments to make observations or to endorse the concerns of their industry. Finally, the assessments are examined by the Impact Assessment Board (IAB) – a control body that reports to the President of the Commission. The IAB returns low quality impact analyses to the Directorates of the Commission² with comments on what can and should be improved. Although the IAB is not independent from the Commission, since its technical work is supported by the Secretariat General, it operates at arm's-length from the daily operations of the Directorates General (DGs) that prepare the RIAs.

But the lack of a unitary executive has an important implication for the way better regulation has been institutionalized in Brussels (Allio 2009; Radaelli and Meuwese 2010; Melloni 2011). The reforms of rulemaking have been refracted by the Commission as complex organization that does not respond to a single politician elected in a national constituency. For the Secretariat General of the Commission, RIA has provided the opportunity to consolidate strategic management skills (about policy initiation) and to exercise direction over the DGs – in the past much more autonomous in policy formulation. Since the Secretariat General officials are both part of the teams that build the RIA and custodians of its quality (directly and via the IAB), they have increased resources and capacity for the coordination of cross-cutting issues. Since 2002, there has been a spectacular transformation of the Secretariat General units, from a focus on constitutional issues and the future of Europe to the specialization on better regulation.

Apart from the incentives of the Secretariat General, the process of preparing the RIAs is, at least for the major policy proposal, a matter involving different DGs – each of them with their constituencies and preferences. The activation of a plurality of DGs on the same issue has created opportunities for policy learning – since thanks to the RIA, the same issue is examined accord-

² The Directorates-General or DGs are the departments of the European Commission that cover a specific policy area. They respond to a Commissioner.

ing to different perspectives. Thus, to illustrate, complex proposals such as the air quality strategy of the EU have been examined in their environmental, infrastructural, economic aspects because impact assessment has provided the opportunity and the resources to activate multiple interests and multiple sources of evidence-base.

It is not easy to establish causality in these matters. But the process of preparing RIAs seems to have increased administrative capacity and the opportunities for joined-up mechanisms within the Commission. This goes hand in hand with the strengthening of the administrative role of the Commission, together with other reforms that have increased coordination from the top. There are seeds of important changes in the roles of this important institution (that is, the Commission): its role as political engine of integration is in decline, but not its administrative role. In another project (Radaelli and Meuwese 2010), we have described this as unintended learning. We use the qualification «unintended» because none of the actors involved has ever played the RIA game with the goal of learning. The goals are to control the bureaucracy (for the Member States and the European Parliament), to create capacity for policy coordination at the centre (for the Secretariat General) and to defend a particular constituency (for the DGs). But (still) learning it is – from the organizational perspective at least.

To conclude, institutionalization has proceeded through different mechanisms, i.e., the effects of delegation within the Presidential administration, the role of Courts, and a delimitation of the range of utilization of regulatory oversight in the USA; the politics of institutional balance concerning the bureaucratic monopoly of legislation and the internal organizational politics of the Commission in the EU.

5. From regulation to constitutional dimensions

In this Section we describe the effects of regulation on constitutional politics, looking at four categories of effects. The first category concerns the status of *constitutional values* in the debate on regulatory reform and oversight. For Americans the integration of the administrative state into the constitutional scheme has been one of the big questions of the twentieth century (Rosenbloom 2000a). Not so for the EU architects.

The foundations of the Administrative Procedure Act lie in a constitutional issue: «whose bureaucracy is this, anyway?» (Rosenbloom 2000b, 14). The major players in the game of retrofitting the administrative state to the constitution have been Congress, the President and the Courts (Lubbers 2006).

The Administrative Procedure Act, judicial review and Presidential executive orders have become the cornerstone of this game (Lubbers 2006).

These cornerstones are dynamic. Judicial review cannot be reduced to a single episode. Instead, it has produced a process of long-term learning wherein principles and practice of regulatory oversight and risk regulation have been re-defined (Majone 2010, especially Section IV). As for the Administrative Procedure Act, what matters in constitutional terms is not its establishment in 1946, but its implementation across the decades (Shapiro 1996; West 2005; 2006). Executive orders on regulatory oversight have gradually established a Presidential grip on federal executive agencies, consolidating a unitary executive (Blumstein 2001).

In essence, in the USA, the debates and the political processes of «retrofitting» the administrative state have been infused with constitutional values (Stewart 1975). These are values concerning the legitimate roles of Congress and the President, but also the rights of participation and representation in rulemaking, the proper scope of negotiated regulation, fairness in enforcement (especially with reference to small business), and the constitutional dimension of advice and consultation, as well as the disclosure of evidence (Coglianese 2002) and the «regulatory right-to-know» (Rosenbloom 2000a; Lubbers 2006)³.

These constitutional values were somewhat present in the emergence of the better regulation agenda in Europe (Mandelkern group 2001; European Commission 2001). However, they have been systematically played down as institutionalization progressed. Most likely, the Commission reasoned that the easiest way to get results out of this regulatory reform agenda was to promote its neutrality. Smart regulation, in this political strategy is not a «regulatory philosophy» but a «toolbox». Because having «notice and comment» type rules enshrined in an APA would significantly tie the Commission's feet, it makes sense from an organizational perspective to emphasize the insignificance (for constitutional relationships, not for competitiveness outcomes) of RIA-related rules. In other words: how regulatory trade-offs are being made is best left to a form of technical management by the bureaucracy, rather than discussed in terms of constitutional values.

Second, the constitutional effects differ because EU impact assessment concerns eminently legislative proposals, and in more limited way the level of

³ Rosenbloom (2000a, 41) rightly observes that the APA, the Federal Advisory Committee Act, and the Negotiated Rulemaking Act «open agency rule making to public participation». The Small Business Regulatory Enforcement Act of 1996 «takes their logic one step further: it requires agencies to reach out to small entities which might not otherwise be able to comment effectively on proposed rules or have the opportunity to serve on advisory and negotiating committee».

comitology⁴. This explains why RIA in EU lawmaking affects the relationship between the Commission and the Parliament/Council, and lawmaking *tout court*. By contrast, recall that only federal executive agencies are subjected to RIA. Independent agencies are not covered by the executive orders on costbenefit analysis and oversight by the OMB. Lawmaking activity in Congress contemplates forms of appraisal, but nothing similar to the RIA process used for federal executive agencies. Impact assessment in the EU, therefore, has direct constitutional relevance for the relations among its key institutions.

In fact, the EU's better regulation initiatives have reopened the complex constitutional game of institutional balance with the European Parliament and the Council. The EU has a thin inter-institutional agreement on better lawmaking signed in 2003, not an APA⁵. In the overall constitutional picture the question whether the EP has the right to ask for a revision of an RIA by the Commission (the type of question that popped up in the long overdue negotiations on important regulations) shows an attempt to redraw the boundaries of lawmaking. In 2012 the Council on Competitiveness called on the Commission to involve end-users «in evaluations of regulation in order to identify excessive burdens, inconsistencies, obsolete and ineffective measures. and reduce un-necessary regulatory burdens» (Council, 6675/12; PR CO 8, 20-21 Feb 2012). In the same period, the Council put pressure on the Commission to improve on the analysis of competitiveness effects during impact assessment. This level of detail shows how even a type of test may signal shifts towards the preferences of one institution or another, thus moving the boundaries of institutional balance.

This brings us to the third category: the *position of the executive*. Within the unitary executive of the American constitutional system, there is scope for the use of RIA to «discipline and influence executive action» (Strauss *et al.* 2008, 69; see also Kagan 2001). True, as mentioned, the debate on the role of OIRA-OMB is heated. But there is a hint of widely shared constitutional wisdom in the proposition that the President has the right and the duty to use federal executive agencies to make executive policy. The discussion indeed is on the excesses or distortions of this constitutional role.

⁴ Legislative initiatives are referred to as **«secondary» in the EU, since the «pri**mary» level concerns the Treaties. Following this terminology, comitology is the «tertiary» level.

⁵ The agreement is little more than a general memorandum of understanding when compared to the scale of the constitutional issues raised by use of better regulation procedures among the three main institutions of the EU. The full text of the agreement is available in the Official Journal of the European Union, 2003, C 321/01, 31 December 2003, and on-line at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:200 3:321:0001:0005:EN:PDF.

By contrast, in the EU, characterized by shared powers in a mixed polity (Majone 2005), the executive cannot be reduced to a single entity, an individual. Hence the constitutional scope of RIA lies in the legitimacy of the Commission and the ongoing assertion of its exclusive right of initiative. As Strauss *et al.* put it: «For the EU, impact assessment is much more a device for legitimizing Commission choices in formulating legislative proposals and informing legislators than for controlling a dispersed bureaucracy, although it does play an important role in giving the President of the Commission more control over the various Directorate-Generals» (Strauss *et al.* 2008, 69-70. Thus, on one side of the Atlantic we find constitutional implications defined in explicit terms of influence and discipline, on the other couched in the language of legitimacy.

In turn, legitimacy is a core issue in the constitutional discussion of the exclusive right of initiative of the Commission: if the process is public, transparent, and even contestable by a large number of institutional and noninstitutional stakeholders, what are the consequences for the exclusive right of initiative established by the Treaty? Returning to Rosenbloom's question «whose bureaucracy is this, anyway? » (Rosenbloom 2000b, 14), the unique construction of an exclusive right of initiative for a non-elected institution was designed as a safeguard to protect the general European interest. In a sense, it was a constitutional measure, as it puts the Treaty – through the Commission as its guardian – above the squabbles of the Member States. Although it is a constitutional oddity not to give a parliament a shared right of initiative, this construction survived the latest round of high-level constitutional change (Article 17 section 2 Treaty on European Union). But also here, the European Parliament is using «insignificant» procedures to forge a change in constitutional dynamics, questioning the legitimacy and even the validity of the regulatory option chosen from the RIA by the European Commission as it has done with the Thematic Strategy on Air Quality.

Accountability through other means than democratic representation is the related and last relevant constitutional category we discuss. The level of transparency and the public nature of the EU impact assessment process are up for debate. The Commission is involved in a sophisticated game of give and take when it comes to the openness of the process. On the one hand, the RIA is published only when the proposal is agreed by the college of Commissioners, but it is prepared in a context in which the DGs are open to the stakeholders though a variety of consultation techniques. There has been a constant push from the American side to increase the transparency of the RIA process – for instance by structurally publishing draft RIA reports. In some Member States there is confusion as to whether the preparation of the RIA is yet another opportunity to make the interests of the Member States heard, to produce counter-RIAs, or to respond to domestic pressure groups that feel harmed by the proposal of the Commission.

There is nothing similar in the USA, where consultation takes places on the basis of RIA rather than as an input into the analytical process. Because the constitutional essence is influence and discipline, the preparation of the RIA mainly involves OMB-OIRA and the agency. Once the agency has gone through the OMB hurdles, and both parties (OMB and agency) feel that the analysis has been concluded, then the proposed regulation is published for notice and comment. This is the state where the RIA becomes open to the stakeholders. During the preparation of the RIA, OIRA does not make the documents public or invite participation (Strauss *et al.* 2008). The fact that the process becomes public at a later stage in the USA also explains why consultation is more political in Washington and more technical in Brussels. Strauss *et al.* (2008, 79) explain that in America «a centrally managed, multi-year process of consultation during the drafting process, organized by those responsible for drafting and not by those who hope to influence them politically, is simply unknown».

These differences have left a mark even in the length of documents. The classic American RIA is long and detailed, but the actual rule is rather short. In the EU, we find long directives and (relatively) short RIAs. This is not trivial. It alerts on an important consequence of the four major differences about the role of internal accountability in the USA and the external accountability concerns of the Commission. For the Commission, the RIA process exists to trigger transparency and communication. Impact assessment is above all a method to structure the relationship with the stakeholders for an organization that works primarily via consensus-building. Short RIAs are useful for communication purposes – but the overall legislative quality of long directives can be questioned. In the USA, the long RIAs serve the purpose of internal accountability, that is, accountability of the agency to the President via OIRA.

The balance between various types of accountability is also revealed by the choices made about oversight bodies – that is, the constitutional role of the regulatory quality «custodian». In the USA the role of this custodian – arguably the President – is clear: to ensure that delegated legislation is in line with his political priorities. In the EU, the Impact Assessment Board, which is more like an interim custodian endowed with soft power but the main custodian in practice nonetheless, has an ambivalent role (Wiener and Alemanno 2010). It needs to balance the needs of the institution it is part of (the Commission) to justify its proposals with the calls for objective analysis from legislative stakeholders who cannot achieve this *ex post* in a court room. It is typical of the way the EU is governed that such a pivotal organization (the IAB) is established on a whim, with no one except a handful of «better regulation experts» realizing its existence.

6. Conclusions

This article has contributed to the comparative debate on the USA and the EU by drawing on a conceptual framework of regulatory constitutionalism originating in socio-legal studies and political science. We have shown that while the grand constitutional debate of the last decade has been dominated by the issues concerning a possible constitution for Europe and the TFEU, a quiet constitutional change was under way in the field of rulemaking.

To understand this process of change, it was useful to contrast the EU with the US case considering classic dilemmas posed by the politics of (post) delegation. Our analysis shows that the institutionalization of smart regulation has proceeded through different mechanisms in the two cases. The effects of regulatory change on constitutional politics also differ, at least in four important categories. We have argued that the constitutional effects of regulatory oversight really do depend on issues that may prima facie seem details when compared to large-scale Treaty change. Perhaps regulatory procedures are anticipating constitutional movements that the EU is not quite ready for. In short, our findings add new dimensions for the analysis of two regulatory states that are similar at the level of the most abstract principles, but seem to differ when looked at from the perspective of rulemaking procedures.

Our findings have direct implications for those who do comparative research on constitutional issues. Regulatory oversight mechanisms have been «retrofitted» to the American constitutional framework. But RIA procedures are gradually shaping up (and often heating-up!) constitutional issues that up until now have been too difficult to settle at the formal constitutional level in the EU. These issues revolve around the constitutional values of the administrative state, institutional balance, the executive function, and accountability. These dimensions provide future research with a set of new conceptual hooks to grasp the relationship between constitutionalism and regulation.

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