Executive rule-making: procedures in between constitutional principles and institutional entrenchment

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1. INTRODUCTION

EU executive rule-making, as a phenomenon distinct from law-making *tut court*, has been the subject of significant institutional and academic discussion in EU law. The distinction between ‘measures directly based on the Treaty itself’ and ‘derived law intended to ensure their implementation’ animated since the 1970s the debate on the legal and institutional limits of implementing acts, including on the relative competence of the Council and of the Commission in this respect.¹ Since the Lisbon Treaty, with its new scheme of delegated and implementing acts – distinct from legislative acts in the sense of Article 289(3) TFEU – much of the discussion has shifted to the distinction between these two types of acts, an issue which recent Court judgments have not clarified.²

EU executive rule-making is far from being limited to the acts now recognized in the Treaty. In a broad sense, it includes all non-legislative acts of general application that produce external effects by concretizing the content of Treaty provisions or legislative acts and defining the criteria for the regulation of specific cases.³ Formally,

³ This definition relies on the ReNEUAL Model Rules on EU Administrative Procedure – Book II
acts of general application adopted directly on the basis of the Treaty outside of legislative procedures are executive rule-making. Guidelines, plans, publicly recognized private standards can also fall within this category. Insofar as they produce external effects, these different types of acts have in common the capacity to impact on rights and legally protected interests of natural and legal persons, as well as the ability to shape the acts of other public entities. EU law has developed a set of constitutional and legal principles that ought to frame the way in which executive rules are made, in view of the external effects that they produce, beyond the definition of inter-institutional relations or the division of tasks or collaboration between the EU institutions and Member States.

This chapter starts by pointing out that, for institutional reasons specific to the EU, executive rule-making has been conceived in a way that ignored the structuring and control functions of administrative procedures. It continues by mapping the scope and nature of executive rule-making, as well as the various forms it can take. These indicate the varied and extensive use that the EU institutions and bodies make of executive rule-making. This variety poses difficulties for a single set of procedural rules governing executive rule-making (Section 2). Despite these difficulties, it is argued that the Treaty provisions on democracy, in particular Articles 9 and 11 TFEU, would require a systematic consideration of how the principles of transparency and participation – constitutionally framed as dimensions of democracy – should imbue the exercise of authority that executive rule-making represents. How much of a challenge this normative claim represents largely depends on how legal rules on access to

documents, reason-giving and careful examination, and institutional practices of participation (which largely fill in the absence of legal rules) apply to executive rule-making (Section 3). They may contribute to structure the discretion of those who make executive rules and the relationship between the authors of these rules and legally affected persons and citizens. However, the chapter argues that the case law on access to documents and on participation may be entrenching the way the Commission shapes rule-making, rather than developing ways of structuring those procedures in view of the Treaty provisions on democracy. It discusses also the role that a possible law on the administrative procedure could have in this regard and the obstacles to including rule-making in such a law (Section 4).

2. **MAPPING EU EXECUTIVE RULE-MAKING**

(a) **Differentiation, Institutional Focus, and Proceduralization**

Rule-making procedures – with some exceptions – have been approached in EU law largely as a matter for the institutions, of the way they relate to each other and to the Member States. When formalized, they are predominantly directed at combining the intervention of institutions, agencies, and committees, in a way that is, first, compatible with the Treaty, second, consonant with the interpretation that each institution has of its institutional prerogatives under the Treaty, and third, heedful of the involvement of the national administrations that implement the rules adopted (as well as the participation of interested legal persons, mostly via consultations and advisory groups). In other words, rule-making procedures have been mostly conceived outside the remit of the controls that administrative law would typically provide.

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The focus on the relative powers of the institutions and of the Member States has its genesis in the institutional struggles that have characterized subordinate legislation since the inception of EU integration. The founding Treaties did not differentiate between legal acts adopted directly on their basis and ‘derived’ legal acts (i.e. those that implement the acts of the institutions and on the basis of which they are enacted). Nevertheless, institutional practice (endorsed by the Court) soon determined the need for an additional layer of regulation, for reasons similar to delegation of powers in national legal systems. These were the origins of implementing acts adopted via comitology procedures.

The conferral of powers of the Council in the Commission disrupted an institutional system that had been designed to balance the two institutions – one ‘intergovernmental’, the other ‘supranational’ – that were at the time the motor of European integration. The differentiation between ‘the measures directly based on the Treaty itself and derived law intended to ensure their implementation’ entailed different procedures, which represented an institutional arrangement different from the one established in the Treaty for the adoption of primary acts. The institutional struggles that have characterized comitology since the outset have generated different settlements at different points in time, culminating in the current Treaty distinction between delegated and implementing acts.

5 Despite Article 155, 4th indent of the Treaty of Rome (the Commission would ‘exercise the powers conferred on it by the Council for the implementation of the rules laid down by the latter’).


8 Case 25/70 Koster, [6]; Rey Soda, [12]. On the possible consequences of such power vis-à-vis private parties, see Judgment in Case 5/77 Tedeschi v Denkavit EU:C:1977:144, [51]–[57].

This institutional perspective has relinquished other important functions that procedures could have in ensuring the legitimacy of executive rule-making. Apart from determining and organizing the relative powers and duties of the various entities involved in decision-making, procedures also rationalize public action in ways that go beyond the logic of the relative competences of the participating entities. They enable the management of information required to adopt decisions and structure the scope of available options, inter alia, by enabling the weighing of competing public interests in view of those that, by force of a Treaty or legislative provision, should be pursued in each instance.\(^\text{10}\) In addition, they structure the relationships between decision-makers, legally affected persons and citizens. They provide access points to citizens and persons affected, be it in the form of access to information or access to decision-making. They ensure the impartiality of decision-making and the control of the choices made via reason-giving requirements. Some of these dimensions are not absent from EU executive rule-making, by force of general principles of law and Treaty rules (in the case of reason-giving). Yet, the way such general principles do apply to EU executive rule-making, if at all, is not always clear.\(^\text{11}\)

As the above indicates, the relatively marginal role that rules of the administrative procedure play in the horizontal regulation of executive rule-making in the EU may be explained both by the specific features of the EU polity (in particular the lack, until recently, of an explicit constitutional differentiation between an executive and a legislative function) and by the specific way in which executive rule-making evolved therein. Nevertheless, these specificities should not overshadow the normative discussion on the possibilities to develop a procedural framework that would structure

\(^{10}\) See, inter alia, Curtin, Hoffman and Mendes (n 3) 3–4 and the references made therein. The argument made here is also developed in Mendes (n 4); Case 25/70.

\(^{11}\) See Section 3, below.
rule-making in ways that go beyond the inter-institutional concerns and vertical divisions of executive power that are characteristic of the EU. Executive rule-making is a central feature of the EU political system, not least given the wide scope of issues that may be regulated in this way.

(b) Scope and Nature

The blurred line between what should be regulated in legislative acts and what may be delegated to executive rule-making is indicative of the breadth of matters that may be regulated via executive rule-making. Reflecting previous case law, the Treaty now ‘reserves’ to legislative acts the regulation of the ‘essential elements of an area’. The question is what are these essential elements.

In the Schengen Borders Code case, the Court indicated that essential elements refer to ‘political choices falling within the responsibilities of the European Union legislature’. The Court did not imply that all ‘political choices’ pertain to the competence of the legislator. In a circular way, it indicated that it should be for the EU legislator to rule on those political choices that fall within its responsibility. While not clarifying what such political choices would be, the Court gave three important indications. First, the determination of what is ‘essential’ must be based on objective factors subject to review of the Court, in view of the particularities of the domain concerned. Secondly, those choices may qualify as essential insofar as they entail an

12 See Section 3(a) below.
14 Case C-355/10 Parliament v Council EU:C:2012:516, [65]. This judgment was issued after the adoption of the Treaty of Lisbon, but still under the previous Treaty rules. In a sense, it makes the transition between the previous case law and the Lisbon scheme of non-legislative acts.
15 Ibid, [67, 68].
assessment of conflicting interests.\textsuperscript{16} Third, provisions that contend with fundamental rights to a significant extent also require the involvement of the EU legislature.\textsuperscript{17} By underlining that implementing powers relate ‘only to certain detailed practical rules’, as specified in the applicable rules, the Court appeared to create a fairly broad reserve for the EU legislator.\textsuperscript{18} Often, ‘detailed practical rules’ are equated with technical matters, in particular with regard to implementing acts.\textsuperscript{19}

Yet, the distinction between ‘political choices’ and ‘detailed practical [or technical] rules’ is deceptive, as the Court has also acknowledged. In \textit{Europol}, it ruled that decisions entailing ‘certain compromises with technical and political dimensions’ may not qualify as ‘political choices falling within the responsibilities of the European Union legislature’, provided that the EU legislator has defined the principle guiding such choices, the objectives to be pursued and the legal framework within which such decisions ought to be made.\textsuperscript{20} Also when assessing whether the Commission stayed within the limits of its implementing powers, the Court refers to the general aims defined by the EU legislator.\textsuperscript{21} Perhaps surprisingly, in view of the \textit{Schengen Borders Code} and of the data protection issues at stake in \textit{Europol}, the Court held in \textit{Europol} that the potential impact on fundamental rights was not sufficient to determine a reserve of the legislator.\textsuperscript{22}

The fact that the Court has endorsed the legality of implementing acts defining the temporary suspension of third countries from the list of countries whose nationals

\textsuperscript{16} Ibid, [76].
\textsuperscript{17} Ibid, [77].
\textsuperscript{18} Ibid [72].
\textsuperscript{19} See, e.g., the allegations of the Parliament in EURES, [32]; the allegations of the Commission in Judgment in C-88/14 \textit{Commission v Parliament}, EU:C:2015:499, [21].
\textsuperscript{20} Case C-363/14 \textit{Parliament v Council} EU:C:2015:579, [51] (see also [50]).
\textsuperscript{21} Case C-65/13\textit{Parliament v Commission} EU:C:2014:2289, [48]–[58] and [59 et seq].
\textsuperscript{22} Case C-363/14 \textit{Parliament v Council}, [52]. And see E Tauschinsky, ‘SBC (C-355/10) vs Europol (C-363/14): What does the Court do with fundamental rights and essential elements?’ on the ACELG blog for 2015/09/24.
are exempted from visa requirements and the list of third countries with which Europol may conclude international agreements should at the very least guard against too quick assumptions regarding the technical nature of this category of non-legislative acts.23

(c) A Varied Spectrum of Forms and Authors

As much as institutional practice led to differentiating legal acts adopted on the basis of the Treaty and legal acts that implement them (in a broad sense), it also gave rise to a wide variety of forms of executive rule-making. In a broad sense, these include Council regulations in the area of anti-dumping, and acts adopted by the Commission directly on the basis of the Treaty.24 Quite different phenomena are private regulatory acts. Privately set product standards may acquire the authority of a public act in schemes such as the ‘new approach to harmonisation’ (e.g. via presumptions of conformity, or recognition and incorporation into legal acts of the institutions and bodies). They too convey the distinction between the realm of law-making, where essential requirements are set, and the realm of technical stipulations, defined via distinct procedures and institutional arrangements, which, in this case, arguably coalesce private autonomy and public authority.25 They involve more than just implementation or concretization of political choices made by the Council and the Parliament, which may explain the stress put on the openness and transparency of these rule-making processes.26

23 See, respectively, the acts at issue in C-88/14 Commission v Parliament EU:C:2015:499 and in Case C-363/14 Parliament v Council above.
24 See, e.g., Arts 43(3) TFEU and 108(4) TFEU and Art 126(9) TFEU (although addressed to a Member State).
Rule-making may also come in the form of communications, guidelines, frameworks, notices, recommendations, insofar as these may contain or generate normative criteria of decision-making. They may do so by indicating how the EU institutions or bodies interpret EU law (and would, therefore, enforce it), which course of action they intend to take on a given matter, or how Member States should coordinate their implementing actions. Such informal acts have a prominent role in EU law, which varies according to policy area. In particular (but not exclusively) in the area of state aids, guidance has also allowed the Commission to define and develop its own policy. Guidance may also occupy the normative space left open by framework norms, serving the uniform application of EU law in ways that largely exceed the interpretation of legislative norms.

The ability of such informal acts to generate external effects is not always clear. The EU Courts have recognized that informality does not equate with lack of legal effects. The publication of guidelines defining a course of action may have a self-binding effect on the Commission, insofar as they define rules from which it cannot deviate at the risk of breaching general principles of law, such as equal treatment or the protection of legitimate expectations. As a result, the Commission may only depart from them by giving reasons that justify deviation and safeguard those principles.


29 See Joined Cases C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P Dansk Rørindustri and Others v Commission [2005] ECR I-5425 (EU:C:2005:408), [211]; Case C-75/05 P
Nevertheless, it remains difficult to determine when guidance documents create new legal obligations or are liable to bind the Commission’s own discretion by force of general legal principles of law, and when they are only internal guidelines not intended to have legal effects.\(^{30}\) The capacity such acts have to shape both Member States’ implementing actions and the conduct of legal persons raises concerns regarding the procedural norms they would be subject to, in particular to the extent that they may largely fall outside the scope of judicial review.\(^{31}\) The balance between the flexibility that, within the legal limits of its authority, the EU executive should have to perform its functions adequately, and the application of procedural rules or general principles of law that would structure their discretion is particularly delicate and difficult to strike in this case.\(^{32}\) Arguably, in view of their potential effects, the making of such acts should be subject to a minimum level of formality, which some EU agencies already follow, and to guarantees that would ensure that guidance is not a means of circumventing existing procedures and the guarantees they enshrine.\(^{33}\)

Rule-making not only may come in different forms, but also may be adopted by different authors, unilaterally or in collaborative forms, as may be the case with some informal guidance, and with private standards that enjoy a presumption of compliance. Significantly, EU agencies also have rule-making powers. While not all agencies have the formal competence to adopt rules, quite a few regulate their respective sectors via informal regulatory instruments (such as best practices).\(^{34}\) In addition, some participate

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\(^{30}\) Scott (n 28) 342–43. An additional obstacle to review is the authorship of these acts, Scott, ibid, 337–39.

\(^{31}\) Ibid, 346. Scott addresses in particular the risk that guidance may deviate from the wording and telos of the legislative acts the implementation of which they are intended to facilitate.

\(^{32}\) See ReNEUAL – Book II (explanations) (n 3).

\(^{33}\) Scott (n 28) 351–52.

\(^{34}\) E.g. ECHA provides ‘technical and scientific guidance and tools where appropriate for the operation of [the Chemicals Regulation] in particular to assist the development of chemical safety reports … by
in the process of making legally binding non-legislative rules. The financial agencies, in particular, combine both types of power and, as many commentators have noted, stretch the rule-making powers of agencies in an unprecedented way.

These selected examples indicate the broad range of normative acts that support the expanding administrative functions of the EU, loosely understood as those that provide criteria to apply and adjust the content of legislative acts or of Treaty provisions to concrete situations. They point both to the substantive relevance of executive rule-making in EU law and to the difficulties of placing these various acts under a single set of procedural rules that would shape them in view of the Treaty-based principles and of the legal requirements that stem from the Courts’ case law.

3. CONSTITUTIONAL AND LEGAL FRAMING OF EU RULE-MAKING

(a) Constitutional Change, Normative Promise and Legal-Institutional Practice

The Treaty of Lisbon introduced, for the first time at Treaty level, the organic and procedural distinction between legislative and non-legislative rules, which previous case law and institutional practice had carved out. It also defined provisions on democratic principles. As ‘founding’ principles, they ought to imbue the functioning of the EU political system, including the procedures through which the EU adopts


37 Curtin, Hoffman and Mendes (n 3) 2. On the difficulties of identifying an executive function in the EU, see D Ritleng, ‘L’identification de la fonction exécutive dans l’Union’ in J de la Rochère (ed), L’exécution du droit de l’Union, entre mécanismes communautaires et droits nationaux (Bruylant 2009) pp. 27-51.

38 See explanations of ReNEUAL Model rules – Book II, in particular 41, 50–53. See also Curtin, Hoffman and Mendes (n 3) (arguing that executive rule-making should concretize constitutional values and principles, rather than being shaped mainly by result-oriented choices)
executive rules.\textsuperscript{39} Those provisions endorse transparency and participation as part of the democratic foundations of the EU.\textsuperscript{40} The Treaty also squarely addresses the relationship between the EU institutions and citizens (Articles 9 and 11 TEU).

Notwithstanding the ambiguity of these Treaty provisions, both their systematic insertion in the Treaty and their wording acknowledge (in the case of transparency) and trigger (in the case of participation) a normative understanding of these principles as dimensions of democracy, which is qualitatively different from their understanding as good governance practices.\textsuperscript{41} Transparency and participation ought to enable citizens and their representative associations to engage in the definition and implementation of public policies and to voice their rights and legally protected interests, in equal terms (Article 9 TEU). In this perspective, the emphasis is placed on these principles’ ability to structure the relationship between public authority and those subject to it, rather than on their contribution to enhance problem-solving capacities and the effectiveness of rules – aspects which managerial theories of public administration would tend to emphasize.

Arguably, these Treaty provisions constitute normative yardsticks that ought to frame and constrain the exercise of authority in the EU and, hence, justify rethinking the existing approach to rule-making procedures in the EU as essentially a matter of the

\textsuperscript{39} On founding principles, see A von Bogdandy, ‘Founding Principles’ in A von Bogdandy and J Bast (eds), \textit{Principles of European Constitutional Law} (Hart Publishing 2010) in particular at 21–23. On the ability of the Treaty provisions on democracy to frame the procedures leading to the adoption of delegated and implementing acts, see Mendes (n 4) in particular, Section 11.4.

\textsuperscript{40} Transparency is a condition of the fulfilment of democracy (Arts 10(3) TEU and 15(1) TFEU). Participation in decision-making beyond representative institutions ought to become a complementary source of democratic legitimacy. See, further, J Mendes, ‘Participation and the Role of Law after Lisbon: A Legal View on Article 11 TEU’ (2011) 48 CML Rev 1849, 1778–79.

\textsuperscript{41} The argument is developed with regard to participation in Mendes ibid, in particular 1861–63. Stressing the normative demand for change does not deny the risks of conflating interest representation with participatory democracy or of the possible shallow legitimating effects of transparency – see further Mendes (n 4) Section 11.4.2. The democratic dimension of transparency had been stated in Judgment in Joined Cases C-39/05 P and C-52/05 P 	extit{Turco v Council of Ministers} EU:C:2008:374.
horizontal inter-institutional balances and vertical divisions of executive authority. In this view, the structural specificities that may explain the marginal role that procedural rules – in the ‘thick’ sense defended above – have in current EU executive procedures no longer justify maintaining the status quo. Procedures should not be designed only on the basis of sector-specific needs, to address institutional conflicts or administrative collaboration, without a systematic consideration of how the authority they embody ought to be structured in view of founding legal principles. At the same time, placing the emphasis on the constitutional framework of procedures ought neither conceal the difficulties that an eventual ‘proceduralization’ could entail, nor obfuscate the need for flexibility in carrying out administrative functions. The main challenges lie in identifying the aspects of rule-making that should be regulated horizontally, the scope of horizontal rules and their combination with sector-specific regulation and specific types of acts in a way that would not stifle the effectiveness of rule-making while still not losing sight of the way public authority should be framed within the current constitutional framework. Addressing these issues requires knowledge about the scope of current rules and institutional practices to ascertain how distanced existing rules and practices may be from the normative requirements of constitutional principles. This is a necessary step to inform the discussion on the role that a general law on the administrative procedure could have with regard to executive rule-making.

**Transparency strictu senso: access to administrative documents**

From a normative standpoint, transparency is a way of securing ‘a more significant role for citizens in the decision-making process and [ensuring] that the administration acts with greater propriety, efficiency and responsibility vis-à-vis the citizens in a

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42 Section 2(a).

democratic system’. The strongest statement of the Court in this regard was perhaps made in the *Turco* judgment, where the Court upheld ‘the democratic right of European citizens to scrutinize the information which has formed the basis of a legislative act’.

The emphasis on the relevance of transparency specifically in legislative procedure enabled the Court to contrast the wide access to legislative documents with a more restrictive approach to access to documents pertaining to administrative activities. In some cases, the Court established general presumptions of non-disclosure that apply to categories of administrative documents. The institutions applying an exception to access (Article 4 of Regulation 1049/2001) may rely on such presumptions, instead of demonstrating a specific and effective harm and a reasonably foreseeable risk to the interests protected by the exceptions (as would follow from *Turco*). General presumptions are intended to preserve ‘the integrity of the conduct of the procedure … by limiting intervention by third parties’. In the first cases where general presumptions were established, these served to safeguard the application of specific regimes on access to file, where sectoral legislation defined the conditions

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45 *Turco* ibid. See *Access Info Europe* ibid, [33].


under which third parties could have access to bilateral procedures involving investigated undertakings or Member States, i.e. single case decision-making.

To the author’s knowledge, the distinction between legislative and non-legislative acts never applied to cases on access to documents produced in the making of general non-legislative acts. However, a 2015 judgment of the General Court on the disclosure of draft impact assessment reports (and of the related reports of the Impact Assessment Board) broke a new frontier on the scope of application of general presumptions of non-disclosure. The Court squarely upheld the application of a general presumption that protects the Commission’s space to think in ongoing decision-making procedures ‘regardless of the nature – legislative or otherwise – of the proposal envisaged by the Commission’. The sweeping way in which the Court admitted a general presumption as virtually applicable to any ongoing decision-making procedures of the Commission is noteworthy. The Court grounded the presumption in the Commission’s independence and in its Treaty mandate to act in the general interest. This position contrasts starkly with the purpose of ‘widest possible access’ of the regulation on access to documents, which arguably requires a restrictive interpretation of the exceptions to access. Nevertheless, the Court sought to safeguard the democratic rationale of disclosure in legislative procedures, by pointing out that the Commission does not act in a legislative capacity when it prepares or develops a proposal for an act, ‘even a legislative act’. It acts in the capacity of an independent institution that, because of its role to promote the general interest, must act insulated from external

48 E.g. Case T-121/05 Borax v Commission EU:T:2009:64, [69] on non-legislative regulatory acts seems to confirm this point. See, in the context of international negotiations, the Opinion of AG Sharpston, in Case C-350/12 P Council v In ‘t Veld EU:C:2014:88 (in particular [71]–[72]).
49 Joined Cases T-424/14 and T-425/14 ClientEarth v Commission at [50], [52], [68]–[75], [76]–[78], [100].
50 ClientEarth v Commission [78]–[84].
51 Ibid, [102]–[03].
pressures that could ‘compel the Commission to adopt, amend or abandon a policy initiative’ and hinder the ‘atmosphere of trust during discussions’. 52

Without questioning that moments of transparency ought to be balanced with moments of closed internal deliberations during decision-making procedures, this judgment arguably goes a step too far, in particular by anchoring the presumption on the institutional features of the Commission. The moments of interaction of the institutions with interested parties and the public during rule-making procedures, which the Commission defines via public consultations during impact assessments, 53 seem to be the only ones that the Court is willing to acknowledge as points of access to an otherwise virtually closed procedure. At stake in this case seem to have been possible shortcomings of the impact assessment procedure and the applicant’s desire to complement the information that the Commission held. 54 This possibility could indeed amount to an undesirable ‘exercise of targeted influence’, which the Court rightly intended to avoid. 55 It would have given Client Earth access to the procedure after the closure of impact assessment. Yet, the Court ignores that the Commission itself keeps its door open to receiving input from interested parties outside public consultations. 56 One may query whether the balance between, on the one hand, the need to preserve the space of decision-making of the Commission and, on the other, the moments of access to documents and to the procedure should not be regulated in a different way, e.g. via general rules that would concretize the exceptions on the regulation on access to

52 Ibid, [51], [52], [95], [115].
53 Section 3(a)
54 ClientEarth v Commission [130], [150].
55 Ibid, [96].
56 The 2015 guidelines on impact assessment distinguish between ‘consultations’, which are subject to the minimum standards of consultation, from ‘feedback’ processes, which are not subject to those standards (Commission Staff Working Document, Better Regulation Guidelines COM (2015) 215 final, p. 66, footnote 86).
documents and would balance them against the principle of democracy as enshrined in the Treaty.

**Participation in rule-making: no-law’s land**

Participation in EU rule-making has been and largely remains a principle of governance valued in its ability to enhance problem-solving capacities, process efficiency and policy outcomes.57 Rather than a principle of democracy, which postulates that citizens or their representatives are given voice and equal treatment, in a way that could arguably place external constraints on the way public authority is exercised, participation is seen as a means of asking ‘the right people … the right questions about the right initiatives, so as to feed into Commission decision-making in an efficient manner’.58 There seems to be little, if any, institutional awareness of the normative implications entailed in the way in which the Treaty frames participation.59

Giving voice and equal treatment would arguably require a set of binding procedural rules that would not only shape procedures accordingly, but also ensure the fulfilment of these requirements. A legal approach to participation has however been straightforwardly dismissed by the Court. The reference judgment in this respect remains Atlanta. Here, the Court held that the only obligations of consultation impinging on the EU institutions are those specifically envisaged in the relevant provisions of the Treaties. In the Court’s view, ‘the fundamental democratic principle that the people should take part in the exercise of power through the intermediary of a representative assembly’ excludes direct participation in rule-making procedures.

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except where duties of consultation are explicitly enshrined in a Treaty or legislative provision. 60 When and how participation procedures should be envisaged is a matter for the Member States and for the EU legislator. The Court’s position on this matter combined with the EU legislator’s resistances in defining procedural rules for executive rule-making mean that, with the exception of rare sector-specific rules, there are virtually no participation rights in EU rule-making that would fulfil the function that notice and comment has had in US administrative law.61

Arguably, the above-mentioned arguments that the Court invoked in Atlanta no longer hold in view of Article 11 TEU. Yet, to the author’s knowledge the Court has not been faced with legal claims based on this Treaty Article which could have led it to revisit its case law. One legal reason is the conditions to challenge acts of general scope. 62 A related legal reason is the way applicants formulate their claims of participation. Most likely, they are directed at protecting their individual interests in the face of an act that they consider to have been harmful to their rights or legally protected interests. In this sense, they are much more in line with the rationale of the right to be heard in individual decision-making, than with a democratic rationale of enabling any legal or natural person to voice interests that the applicable legal norms protect and that, accordingly, administrative decision-makers need to pursue when adopting legal acts. While it may not be easy to dissociate one rationale from the other, 63 in the absence of collective actions, Court actions are likely to channel the individual dimension of

60 Case T-521/93 Atlanta and Others v European Community EU:T:1996:18471; Case C-104/97 P Atlanta v European Community EU:C:1999:498, [38]. On the latter argument, see also Case T-135/96 UEAPME v Council [1998] ECR II-2335, [88]. For an analysis of Atlanta, see Mendes (n 57) Chap 5 and Mendes (n 40) 1874–75.
62 Contrary to what I had anticipated in Mendes (n 40) 1873 et seq, the loosening of standing criteria after Lisbon does not appear to have had an impact on the possibility of participation claims reaching the Court. But see further Kieran Bradley, Chap 17 in this volume.
63 See Mendes ibid, 1864.
participation. The emphasis on the protection of the individual’s interests stands in contrast with the collective dimension that the democratic meaning of participation conveys, as an active engagement in public action. The individual dimension is further enhanced by the configuration of the right to be heard as a fundamental right (Article 41(2)(a) of the Charter of Fundamental Rights). Where relied on by applicants, the Court has rejected extending the scope of this fundamental right to acts of general application, in accordance with a third argument that the Court had already invoked in Atlanta: ‘the right to be heard in an administrative procedure affecting a specific person cannot be transposed to the context of a legislative process leading to the adoption of general laws’. The extension of this reasoning to non-legislative acts is problematic, to say the least. Yet, in the absence of legal rules that would frame participation in a way that could concretize it as a founding legal principle in the sense of Article 11 TEU, there are good reasons to avoid that individual rights of participation (that would be established via judicial means) excessively constrain the discretion of administrative decision-makers in adopting acts of general scope. It follows that both for positive legal reasons, pertaining to the current design of rules of standing, and for normative legal reasons, judicial action is not the suitable means to enforce the principle of participation as a dimension of democracy that Article 11 TEU enshrines. It would be primarily the task of the legislator, which has been silent in this respect and is likely to remain so.

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64 On how, from this perspective, participation could complement representation, see Mendes (n 4) Section 11.4.2.
65 Case T-521/93 Atlanta and Others v European Community EU:T:1996:184, [70], [71] upheld on appeal in Case C-104/97 P Atlanta v European Community EU:C:1999:498,[31]-[40]. The Court recently reiterated this argument in Case T-296/12 The Health Food Manufacturers’ Association and Others v Commission EU:T:2015:375, [98], [154], [178].
66 See for further detail, Mendes (n 57) Chap 5.
67 See critically, Mendes (n 4) Section 11.4.3. And see Section 5 below.
In view of the lack of a legal framework, participation in executive rule-making does not formally possess a control function such as would be characteristic of administrative law procedures, as a means to structure the discretion of the Commission in the adoption of such acts. The EU institutional practice of consultations, in particular those that the Commission undertakes in the context of impact assessments, could fill this gap. Consultations, as part of impact assessment procedures, have now been explicitly extended to delegated and implementing acts. Where the conditions exist that may justify impact assessments (i.e. the possibility of ‘significant economic, environmental or social impacts’), these should be ‘carried out for both legislative and non-legislative initiatives as well as delegated acts and implementing measures’.

It thus seems more likely that impact assessments will become a norm also at this level of rule-making, depending on the potential significance of these acts. Consultations are, now as before, part thereof. Yet, without denying the positive aspects of this practice, there are limits to the functional equivalence of such practices with legal rules that would introduce a ‘notice and comment’ type of procedure in line with the normative meaning of Article 11 TEU.

While the intention to extend the scope of consultations appears to be in tune with the wording of Article 11(3) TEU, nothing in the Commission’s guidelines indicates that such processes could have a democratic meaning. They have a different rationale. Consultations occur in the context of impact assessments, which are a tool to

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68 Better Regulation Guidelines (n 56), 17 (emphasis added).
69 Ibid. In addition, the same guidelines indicate that ‘stakeholder consultations can in principle take place throughout the whole policy cycle. However, stakeholder consultations can only be launched for initiatives which have received political validation by the appropriate political level (cf. Chapter II on Planning)’.
70 On the advantages of the current practices, see P Craig, EU Administrative Law (OUP 2012); Harlow and Rawlings (n 43). The Court advanced an argument of equivalence in Case T-296/12 The Health Food Manufacturers’ Association (n 65) at [181].
ensure evidence-based policy-making, or of related means of policy evaluation.\textsuperscript{71} The way the Commission describes the advantages of stakeholders’ consultations reveals the underlying ‘problem-solving approach’ to participation: consultations involve those ‘who will be directly impacted by the policy’ and ‘those who are involved in ensuring its correct application’; it can improve the ‘evidence-base’ of policy-making; it can ‘avoid problems later and promote greater acceptance of the policy initiative/intervention’. \textsuperscript{72} \textsuperscript{73} This approach arguably stands in contrast with the democratic perspective on participation that the systematic insertion of Article 11 in the Treaty conveys.\textsuperscript{74} The purpose is not to ensure equal voice (in terms of access and treatment) to those interested in having a say in public action.

The rationale of impact assessment indicates that the basic reference for voice is the expert, not the person. Nevertheless, it should be noted that the guidelines reveal a concern for inclusiveness of those consulted. \textsuperscript{75} In addition, ‘open public consultations’ are purported to ‘foster transparency and accountability’, which indicates that participation would have an external control function, or at least create the conditions to exercise such control.\textsuperscript{76} Such an external perspective on participation is, however, contradicted by the second function attributed to open public consultations: ‘ensure broadest public validation and support for an initiative’\textsuperscript{77} This specification

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\item\textsuperscript{71} In the words of the Commission, ‘impact assessment is about gathering and analysing evidence to support policymaking’, p. 16.
\item\textsuperscript{72} Better Regulation Guidelines 2015 (n 56) 63–64. Another category of stakeholder indicated is those ‘who have a stated interest in the policy’, which may open up the scope of those consulted to include also those persons who may not have direct expertise in the matter (ibid, 74).
\item\textsuperscript{73} Contrary to prior documents of the Commission on these matters, there is no rhetoric of bringing ‘citizens closer to the Union’, indicating a distancing of the Commission from its earlier governance agenda. For a critical note on such rhetoric, see K Armstrong, ‘Rediscovering Civil Society: The European Union and the White Paper on Governance (2002)’ 8 ELJ 102.
\item\textsuperscript{74} See Mendes ‘Participation and the role of law’ (n 40).
\item\textsuperscript{75} Better Regulation Guidelines 2015 (n 56) 73–76.
\item\textsuperscript{76} Ibid, 76, emphasis added.
\item\textsuperscript{77} Ibid, 76, emphasis added.
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again indicates an approach to participation as an instrument to support the governance process, rather than as a means to ensure that the decision-makers have a suitable representation of the legally protected interests that their decisions may affect and weigh such interests in line with the public interests that the legislator defined in the parent act. This perspective would require giving voice irrespective of regulatory preferences – an aspect that the better regulation approach to participation may not ensure.

In addition, the long list of exceptions to ‘public consultations’ on delegated and implementing acts confirms the broad discretion that the Commission retains in defining the opportunities of participation.78 Among other exceptions, consultations in delegated and implementing acts will not be carried out in instances where the Commission has ‘no (or limited) margin of discretion’. What may involve limited discretion may be disputed, and may be understood extensively. In particular, this category includes ‘acts implementing international standards into EU law’. This exception is potentially quite far-reaching given the varied instances of international regulatory cooperation in which standards defined by global regulatory bodies (often with the agreement of the Commission) become binding on the EU.79

(b) Selected Procedural Duties

The above indicates that there remains an important gap between the normative promises that the Treaty conveys in terms of the principles that should structure the action of the EU institutions, including at the executive level, and existing institutional practices. The provisions on the democratic principles of the Treaty emphasize the relationships between the EU institutions (and bodies) and the world outside the inter-

78 Ibid, 67–68.
organic (Member State–EU) flow of decision-making. This aspect is further reflected in other Treaty provisions, which indicate openness as a normative feature of the work of the EU institutions and bodies (Articles 15(1) and 298(1) TFEU). Such constitutional framing justifies the development of an administrative law of rule-making procedures, which, beyond providing a structure to the multiple intermediary acts of various entities that rule-making requires, would also shape the relationships between the makers of legal acts, legally affected persons and citizens.80 Existing procedural duties that apply to EU rule-making by force of general rules or principles may perform this function: the duty to give reasons and the duty of careful and impartial examination. This section analyses the way in which these duties apply to executive rule-making, and thereby, provides an illustration of existing administrative controls.

**The duty to give reasons**

The duty to give reasons applies to all legal acts of the Union, irrespective of its legislative or executive nature, general or individual scope (Article 296(2) TFEU). This duty has a three-fold function in EU law, succinctly stated early on by the Court: it ‘seeks to give an opportunity to the parties of defending their rights, to the Court of exercising its supervisory functions and to the Member States and to all interested nationals of ascertaining the circumstances in which the [institutions have] applied the Treaty’.81 As such, it enables Member States and other persons concerned to understand why a measure has been adopted. This aspect is relevant not only from a perspective of transparency, but also of control. It is arguably the main reason why this duty features in the Treaties since the 1950s.82 The duty to give reasons also helps the decision-maker

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80 Curtin, Hoffman, Mendes (n 3); Mendes (n 4).
in defining the content of the act, insofar as the legal requirement to give reasons for the choices taken requires a consideration of the various options available.\textsuperscript{83}

The Court has since long established that the scope of this duty ‘must be appropriate to the act at issue’, stressing that ‘it is not necessary for the reasoning to go into all the relevant facts and points of law’ and that compliance with the duty to give reasons ‘must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question’.\textsuperscript{84} This standard is thus flexible enough to lead to different types of requirement, depending also on the nature of the act at issue. For acts of a general scope, the Court has repeatedly held that the duty to give reasons is complied with if it ‘clearly discloses the essential objective pursued by the institution’, adding that ‘it would be unreasonable to require a specific statement of reasons for each of the technical choices’ such acts entail, or ‘the often very numerous and complex matters of fact or of law dealt with in the regulations’.\textsuperscript{85} The way in which the Court reviews compliance with the duty to state reasons, in line with this standard, varies. In some cases, the Court succinctly considers that the institution has justified its choice and hence satisfied the requisite standard;\textsuperscript{86} in other cases, the Court verifies in some detail if the reasons are suitable in view of the legal requirements by which the institution was bound.\textsuperscript{87} Another criterion by which the EU Courts assesses compliance with the duty to give reasons, also with regard to measures of general application, is the

\textsuperscript{83} Ibid, 1401.
\textsuperscript{84} See, e.g., Case T-89/00 Europe Chemi-Con (Deutschland) GmbH v Council EU:T:2002:213, [65] (antidumping); Case C-221/09 AJD Tuna Ltd EU:C:2011:153, [58] (Common fisheries policy). Emphasis added.
\textsuperscript{85} See, e.g., Joined Cases 292 and 293/81 Société Jean Lion EU:C:1982:375, 3898; Case T-89/00 Europe Chemi-Con (Deutschland) GmbH v Council EU:T:2002:213, [66] (antidumping); Case C-221/09 AJD Tuna Ltd, [59] (common fisheries policy).
\textsuperscript{86} E.g. Case T-89/00 Europe Chemi-Con (Deutschland) GmbH v Council, [67] (antidumping).
\textsuperscript{87} Case C-221/09 AJD Tuna Ltd [62-67] (common fisheries policy).
ability of the statement of reasons to enable interested parties to understand the justification of the act at stake.\textsuperscript{88}

The statement of reasons of implementing acts – in the broad sense the term had before the Treaty of Lisbon – is assessed on the basis of an additional criterion: the relationship between the basic and the implementing act may justify a succinct statement of the latter. The reference to the basic act may be sufficient to clarify the reasons for the adoption of the implementing act, if the the basic act provides criteria on the content of the implementing act.\textsuperscript{89} The Court then assesses the adequacy of the statement of reasons given by reference to the provisions of the main act.\textsuperscript{90} The same line of reasoning may apply to acts that are not in a subordinate relationship, but that have been adopted in a given legislative context, which, on the whole, may be sufficient to clarify succinct reasons given by the author of the act.\textsuperscript{91} In addition, when the act at issue is consistent with previous measures a succinct statement of reasons accompanied by reference to other acts may suffice, unless that act ‘goes appreciably further’ than those measures.\textsuperscript{92}

The Court’s careful approach in using its power of review of the duty to give reasons indicates that it intends to maintain, as far as possible, the fragile distinction

\textsuperscript{88}Case T-296/12 The Health Food Manufacturers’ Association v Commission (n 65) at [109]. In a different sense, but also supportive of the argument made above, Case C-445/00 Austria v Council at [50].
\textsuperscript{90}Ibid at [89].
\textsuperscript{91}Joined Cases 292 and 293/81 Société Jean Lion and Others ECLI:EU:C:1982:375, 3898. See also Opinion of AG Verloren van Themaat delivered on 7 October 1982, in \textit{Société Jean Lion and Others}, 3924–25.
\textsuperscript{92}E.g. Case 73/74 Groupement des fabricants de papiers peints de Belgique and Others v Commission EU:C:1975:160, [31]; Case C-295/07 P Commission v Département du Loiret EU:C:2008:707, [44]; Case C-228/99 Silos e Mangimi Martini SpA v Ministero delle Finanze EU:C:2001:599, [28]. In this case the Court held at [30] that the challenged regulation departed from ‘the Commission’s usual practice’ and considered that the brief reasons added to the references to previous acts did not suffice as a statement of reasons.
between reviewing process requirements and the substantive legality of a measure. The Court is in principle unwilling to perform a hard look review on the basis of reason-giving. An ‘ossification’ of rule-making, which has concerned American scholarship, as a result of judicial review is arguably unlikely in the EU. For the same reason, it is unlikely that a possible restatement of this case law in a general law of the administrative procedure would diminish the flexibility that the Court now recognizes to the institutions when providing reasons for acts of general scope.

**The duty of care**

The inclusion of the duty of care (i.e. careful and impartial examination) in this chapter could seem prima facie misplaced. The duty of care refers to the process of collecting the information needed to appraise the relevant factual and legal aspects of a given situation, and the manner in which such information is assessed. It has a protective dimension, since it allows the EU Courts, in particular the General Court, to challenge the legality of administrative acts adopted on the basis of insufficient or inadequate information. Yet, this same protective dimension has led the Courts to acknowledge the limits of extending this duty beyond the limits of adjudicatory procedures. The question then is whether and how this duty applies to executive rule-making.

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93 E.g., Case T-231/06 T-237/06 *Netherlands and Nederlandse Omroep Stichting v Commission* EU:T:2010:525, [79]; Case C-221/09 *AJD Tuna* (n 84) at [60].


96 The landmark cases are Case C-16/90 *Eugene Nolle* (anti-dumping); Case C-269/90, *TUM* (customs).
The EU Courts have indicated the relevance of the duty of care in relation to acts of general application. One example is Animal Trading Company concerning a decision to suspend imports of products in view of a serious threat to health. This was an action for non-contractual liability where the duty of care functioned as an individual procedural guarantee of the companies that had been affected by a general decision addressed to Member States. In other cases, the General Court has held that, in procedures leading up to acts of general application, the duty of care applies as ‘an objective procedural guarantee arising from an absolute and unconditional obligation on the [EU] institution relating to the drafting of [the act] and not the exercise of any individual right’. It is ‘imposed in the public interest’. In a similar vein, the General Court has denied that the duty of care could be a procedural guarantee invoked by complainants in state aid procedures – which, arguably, lead to acts of general scope.

In the case of T-Mobile, the Court of Justice reverted the judgment of the General Court by contesting its argument that the Commission’s obligation to undertake a diligent and impartial examination of a complaint would arise from the ‘right to sound administration of individual situations’.

The objective dimension of this duty has been translated, in the area of risk regulation, into the principles of excellence, transparency and independence that ought to guide scientific assessments of the Commission, the breach of which may be invoked in Court by individuals directly and individually concerned. But beyond this

97 Case T-333/10 Animal Trading Company, [84]–[94].
98 Case T-369/03 Arizona Chemical, [86], [89] concerning the adaptation of a directive to technical progress.
99 Ibid at [88].
100 E.g. Case T-210/02, British Aggregates, [177]. On the nature of state aid decisions, see, Mendes (n 57) Chap 8.
102 See, e.g., Case T-369/03 Arizona Chemical, [88].
precision, and outside the realm of risk regulation, the Courts did not elaborate further on what care could mean as part of proper administrative conduct. This is an aspect that should be concretized in developing an administrative law framing of EU executive rule-making.\footnote{For a normative analysis of how this duty could be developed, see the quite different views defended in Curtin, Hoffman and Mendes (n 3) 14–15, and Mendes (n 95). See also the proposals in ReNEUAL Model rules – Book II, 3.}

4. EU EXECUTIVE RULE-MAKING AND LAW: ENTRENCHING OR CONSTRAINING AUTHORITY?

Notwithstanding the specificities of the EU legal order, EU law has developed a set of constitutional and legal principles that arguably ought to frame the way in which executive rules are made. Procedures should heed the external effects that executive rules produce, and be conceived in a way that structures public authority accordingly, in addition to reflecting the evolving inter-institutional relations or defining a division of tasks or collaboration between the EU institutions and Member States.

The general legal principles that apply to the procedures by which the EU adopts executive rules have been largely developed via case law. The EU Courts have defined their scope and the way in which they structure these procedures, also where general rules apply by force of legislative acts (namely, on access to documents). They have solidified existing institutional practices without examining them through the lens of a democratic rationale of transparency and participation that the Lisbon Treaty now enshrines. In the case of transparency, the argument that access to documents is a means of enabling citizens (and legal persons) to participate in the making of decisions that affect them has prevailed in access to legislative documents (i.e. pertaining to legislative procedures) to the detriment of access to administrative documents insofar
as general presumptions of non-disclosure apply. The application of a general presumption of non-disclosure in the wide way in which it was admitted in *ClientEarth* virtually closes the procedure to access by interested persons or the public, except in the stages that the Commission itself considers it useful to have outside input and to the extent that it wishes to have such input.

While it remains to be seen whether *ClientEarth* will become settled case law, the Courts’ position regarding participation in rule-making was defined in the 1990s and has stayed unchanged, notwithstanding the Lisbon Treaty provisions on democracy. As noted, given standing rules and litigants’ incentives to challenge executive rules, judicial action is not the most suitable avenue to concretize participation as a democratic principle in view of Article 11 TEU. At the same time, current institutional practices of participation, namely via impact assessments, can hardly be considered a functional equivalent to democratic participation, despite indications to the contrary in the case law.

It follows from the above that the EU Courts’ case law, rather than shaping institutional practices in view of constitutional principles, is arguably entrenching institutional practices, maintaining the gap between principles and practices. This observation applies to participation and, in part at least, to access to documents. The case is different with regard to the duty to give reasons and to the duty of careful and impartial examination. The way the Court has shaped the duty to give reasons enables a control function that is important for the concretization of the Treaty principles (even if this duty serves also other rationales), while ensuring enough flexibility that avoids excessive procedural constraints. The duty of care may serve such a function, but the way it applies to rule-making still needs to be concretized.
The EU legislator would be better placed than the Courts to define a different way of structuring EU rule-making procedures, more heedful of democracy as a founding principle of the EU legal order. But there are also considerable obstacles to this avenue, for legal and institutional reasons. First, there are doubts on whether Article 298(2) TFEU could serve as a legal basis for a law on administrative procedure, which would include rule-making. One may question to what extent the adoption of delegated and implementing acts, as categories of legal acts that procedural rules on rule-making would cover, is a task of the ‘European administration’ in the sense of Article 298(1) TFEU. Doubts may also arise on whether Articles 290 and 291 TFEU exhaust the legal framework that defines the rules to which acts should be subject. Both are surmountable objections. More difficult to overcome are the resistances of the institutions with legislative power. A legislative initiative depends formally on the Commission, whose powers would be constrained by effect of such a law. The Commission’s proposal that preceded the inter-institutional agreement on better lawmaking is revealing of its position on this matter. It made its way to the final text of the agreement, which specifies, first, that the procedures for the adoption of a delegated act are those agreed upon in the new ‘common understanding’ and in that agreement; and, second, in relation to implementing acts, that the institutions agree to ‘refrain from adding, in Union legislation, procedural requirements, sui generis procedures or additional roles for committees, other than those set out in [the comitology regulation]’. It is likely that also the Council would not have enough incentives to

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105 I owe those two points to a discussion with Herwig Hoffman. On my objections, see J Mendes, ‘Delegated and Implementing Rule-Making: Proceduralisation and Constitutional Design’ (2013) 19 ELJ 22 albeit without referring to the legal basis, and J Mendes (n 4) Section 11.4.3.
pass a procedural law applicable to rule-making. The positions of the Commission and of the Council may partially explain the silence of the Parliament in this regard.

In addition to legal issues and institutional resistances, the variety of forms in which executive rules may be adopted in the EU is a challenge to the definition of general rules of procedure that would concretize constitutional principles in a horizontal way. Suggesting concrete rules means struggling with complex trade-offs and entails costs and imbalances that need to be carefully considered. However, these should be seen as a part of a discussion on procedural design that should be constitutionally informed, rather than as insurmountable obstacles to the definition of procedural rules.

At the same time that the EU legislator is avoiding the definition of constitutionally informed procedural rules for the adoption of EU rule-making, a further entrenchment of current institutional practices may occur via international regulatory cooperation, in particular under a putative Transatlantic Trade and Investment Partnership (TTIP). The current Commission’s textual proposal on regulatory cooperation includes impact assessment procedures and consultations, which would apply to domestic procedures, very much in line with the Commission’s current practices. Some of the novelties of the Commission’s better law-making agenda announced in May 2015, in particular the extension of impact assessments, including consultations, to delegated and implementing acts may be a reaction to the TTIP

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107 Generally, on incentives of legislators in passing laws on the administrative procedure, see S Rose-Ackerman ‘Democratic Legitimacy and Executive Rulemaking: Positive Political Theory in Comparative Public Law’ in J Mendes and I Venzke (eds), Allocating Authority: Who Should Do What in European and International Law? Hart Publishing (forthcoming)


negotiations. They were arguably seen as a means of bridging the regulatory differences between the EU and the US in what comes to executive rule-making, in particular the lack of a notice and comment procedure applicable to EU rule-making. This modification to EU procedures will most likely remain (at least until a further reform of better regulation), irrespective of the fate of TTIP. While the shortcomings of such a path have been pointed out above, the continuity between the Commission’s better regulation agenda and its proposals for regulatory cooperation is noteworthy. If this agreement were concluded in the terms the Commission proposed, it would become binding law, incorporated in EU law, and it would define in some respects at least the procedural rules for EU executive rule-making (and law-making). In this scenario, these rules would be shaped by an international agreement on trade and investment liberalization, relying on regulatory practices largely defined by executive actors.

It follows that EU executive rule-making may be at a watershed point. If governed by a law on the administrative procedure that would concretise the Treaty provisions on democracy, this could be a first step to constitutionalizing rule-making. Executive rule-making would then be shaped by constitutional principles. This unlikely scenario contrasts with the trend, visible in the Courts’ case law, to entrench existing institutional practices along the lines of better regulation, as defined mainly by the Commission. The EU’s rule-making procedures are largely shaped by the Commission practices, in view of functional needs of regulation, in contrast to the US rule-making procedures, where, in addition to regulatory impact assessments, the Administrative Procedural Act of 1946 defines the terms of rule-making in a way that - formally at least - ensures equal voice and treatment to any person interested in having a say in the procedure and the ancillary means of redress.