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Joana Mendes

Rule of Law and Participation: A Normative Analysis of Internationalised Rulemaking as Composite Procedures

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TOWARDS A MULTIPOLAR ADMINISTRATIVE LAW:
A THEORETICAL PERSPECTIVE

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Rule of Law and Participation:
A Normative Analysis of Internationalised Rulemaking as Composite Procedures

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Prologue:

Towards a Multipolar Administrative Law: A Theoretical Perspective

The idea that administrative law concepts can remain stable over time has been abandoned. Today, administrative agencies are no longer conceived of as simply executive "machines" and command-and-control bodies. There is a growing tension within countries between the executive branches and social expectations for rights-based institutions, and administrative bodies accordingly develop in an increasingly interstitial and incremental manner. This also happens because the separation of society and administration is less clear, and the public-private dividing line has blurred: dual relationships are becoming an exception; networking and multipolar linkages between norms, actors and procedures are the rule. Legal systems have become more interdependent, due to the import-export of administrative models: this has several implications, such as the fact that some basic principles of administrative law beyond the State have been developing. Furthermore, economic and political analyses of public administrations are increasing; this requires the adoption of multi-disciplinary approaches in examining the field.

All these phenomena – to name but a few – constitute the main features of an emerging "multipolar administrative law", where the traditional dual relationship between administrative agencies and the citizen is replaced by multilateral relations between a plurality of autonomous public bodies and of conflicting public, collective and private interests. For a long time, administrative law was conceived as a monolithic body of law, which depended on its master, the modern State: as such, administrative law was intended to be the domain of stability and continuity. Continuity in the paradigms for study paralleled the idea of continuity in administrative institutions. However, from the last quarter of the 20th century, both assumptions became obsolete. Administrative institutions have undergone significant changes, due to several factors such as globalization, privatization, citizens' participation, and new global fiscal responsibilities. Thus, it is necessary to review the major transformations that took place in the field over the last 30 or 40 years, and to address the consequent transformations in the methods used to study this branch of law.

To analyze this emerging multipolar administrative law, the first objective should be to decouple the study of administrative law from its traditional national bases. According to this tradition, administrative law is national in character, and the lawyer's "ultimate frontier" is comparison, meant as a purely scholarly exercise. On the contrary, administrative law throughout the world is now grounded on certain basic and common principles, such as proportionality, the duty to hear and provide reasons, due process, and reasonableness. These principles have different uses in different contexts, but they share common roots.

A second objective would be to consider each national law's tendency toward macro-regional law (such as EU law) and global law. While the leading scholars of the past labored (to a great extent in Germany and Italy, less so in France and the UK) to establish the primacy of national constitutional law ("*Verwaltungsrecht als konkretisiertes Verfassungsrecht*"), today the more pressing task is to ensure that the

increasingly important role of supranational legal orders is widely acknowledged. Whereas administrative law was once state-centered, it should now be conceived as a complex network of public bodies (infranational, national, and supranational).

A third objective should be the reconstruction of an integrated view of public law. Within legal scholarship, constitutional law, administrative law, and the other branches of public law have progressively lost their unity: for instance, constitutional law is increasingly dominated by the institution and practice of judicial review; most administrative lawyers have been overwhelmed by the fragmentation of legal orders, which led them to abandon all efforts at applying a theoretically comprehensive approach. The time has come to re-establish a unitary and systematic perspective on public law in general. Such an approach, however, should not be purely legal. In the global legal space, the rules and institutions of public law must face competition from private actors and must also be evaluated from an economic and a political point of view.

To better analyze and understand such a complex framework, to elaborate and discuss new theories and conceptual tools and to favor a collective reflection by both the leading and the most promising public administrative law scholars from around the world, the Jean Monnet Center of the New York University (NYU) School of Law and the Institute for Research on Public Administration (IRPA) of Rome launched a call for papers and hosted a seminar (http://www.irpa.eu/gal-section/a-multipolar-administrative-law/). The seminar, entitled "Toward a Multipolar Administrative Law – A Theoretical Perspective", took place on 9-10 September 2012, at the NYU School of Law.

This symposium contains a selection of the papers presented at the Seminar. Our hope is that these articles can contribute to the growth of public law scholarship and strengthen its efforts in dealing with the numerous legal issues stemming from these times of change: discontinuity in the realm of administrative institutions requires discontinuity in the approaches adopted for studying administrative law.

Sabino Cassese, *Italian Constitutional Court*

Giulio Napolitano, *University of "Roma Tre"*

Lorenzo Casini, *University of Rome "Sapienza"*

RULE OF LAW AND PARTICIPATION: A NORMATIVE ANALYSIS OF INTERNATIONALISED RULEMAKING AS COMPOSITE PROCEDURES

By Joana Mendes[*]

Abstract

Procedural standards of participation have the capacity to structure and constrain the exercise of authority. Focusing on the way decisions are formed, this paper argues that the depletion of such standards in processes of reception of trans- and international decisions within the EU potentially leads to situations of unrestrained authority and can constitute a challenge to the rule of law. The first part of the paper identifies the conditions under which this may occur. It sets out the basis for a conceptual and normative analysis underpinning the argument that procedural standards of participation can be considered part of the rule of law.

As such, the depletion of procedural standards emerges as one facet of a broader problem – the ability of public law to structure discretion and constrain the exercise of authority that results from internationalised procedures. These intertwined decision-making procedures cutting across different levels of governance challenge law's ability to limit executive action and, hence, the rule of law premise that the exercise of public authority ought to be limited by law. In this way, and despite its EU focus, the paper contributes to analysing the challenges and possibilities of the rule of law in the current realities of diffusion of power resulting from internationalisation.

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Different versions, with ideas that were in the meanwhile set aside, were successively discussed at the 3rd AUSTAT International Workshop on Authority Beyond States (Paris, May 2012), at the Seminar "Toward a Multipolar Administrative Law – A Theoretical Perspective" (NYU, September 2012), at the Vrije Universiteit (Amsterdam, March 2013), at the European University Institute (Florence, March 2013) and at the London School of Economics (London, March 2013). The paper has highly benefited from the insights of the respective participants, for which I am very grateful. I would like to thank in particular the organizers of the Seminar "Toward a Multipolar Administrative Law" (Sabino Cassese and Joseph Weiler), Benedict Kingsbury, Carol Harlow, Damian Chalmers, Edoardo Chiti, André Nollkaemper and Herwig Hofmann, for their input in the later versions.

This perspective requires a re-conceptualisation of the decision-making procedures that operate the substantive coordination between the sites of governance involved. The processes through which inter- and transnational rules and decisions are received in EU law are only segments of a broader regulatory cycle initiated by inter- and transnational bodies – of which the receiving authorities are either members, observers, or, otherwise active collaborating parties. Such processes can neither be fully grasped by focusing only on the segments of decision-making developed within each legal system, nor can the challenges they pose to law be apprehended from this perspective. They ought to be seen in their entirety as segments of a broader regulatory cycle. On this basis, the second part of the paper proposes two possible routes to rethink internationalised procedures.

Table of contents:

1. Internationalised rulemaking and procedural standards of participation

The provision of public goods depends increasingly on decisions adopted by a variety of bodies at different levels and sites of governance. Internationalisation is one factor of this diffusion of decision-making power. In the EU and elsewhere, regulatory policies are often defined and decisions are taken under the influx of acts adopted in international fora. Substantive issues pertaining to the food we eat, to the testing of pharmaceuticals, to the risks of hazardous substances and chemicals increasingly depend on rules and decisions adopted internationally or trans-nationally, are then transposed into EU law, and thereby filtered into national laws.[1] Decisions proceeding from a variety of external fora are incorporated in EU law, be it through formal procedures of transposition or via administrative collaboration. The source of legal authority of the decisions received may be uncertain;[2] nonetheless, they may acquire an undisputable legal character by the fact of reception or, at least, a normative constraining effect they lacked at the international or transnational level. To the extent that this is the case, the intersection between EU law and inter- and transnational regulatory regimes opens new paths of public action.[3] At the same time, as previous research has shown, procedural standards that structure decision-making within the EU – among them, those that set the terms of participation – tend to be weaker in the segments of EU law that result from the reception of international and transnational

[1] For examples, see Joana Mendes, *EU law and global regulatory regimes: hollowing out procedural standards?* 10 INTERNATIONAL JOURNAL OF CONSTITUTIONAL LAW, Symposium "Public Authority in Global Governance", (2012) pp. 988-1022, and Joana Mendes, *Administrative Law Beyond the States: Participation at the Intersection of Legal Systems* in GLOBAL ADMINISTRATIVE LAW AND EU ADMINISTRATIVE LAW. RELATIONSHIPS, LEGAL ISSUES AND COMPARISON (Edoardo Chiti and Bernardo Mattarella eds., Springer, 2011) pp. 111-132. For the US, see Stewart, *The Global Regulatory Challenge to US Administrative Law*, 27 NYU JOURNAL OF INTERNATIONAL LAW AND POLITICS 695, at pp. 703-705 (2005), who argues that this exposure to the influence of global regulation marks a third phase of evolution of US administrative law (p. 698, 715). See also David Livshiz, *Updating American Administrative Law: WTO, International Standards, Domestic Implementation and Public Participation*, 24 WISCONSIN INTERNATIONAL LAW JOURNAL 961 (2007). The literature on the expansion of global regulatory regimes is extensive. See, for example, Cassese *Administrative Law Without the State? The Challenge of Global Regulation*, 37 NYU JOURNAL OF INTERNATIONAL LAW AND POLITICS 663, pp. 670-673 (2006).

[2] E.g. reception is grounded on a functional argument not captured by the formally assumed international commitments of the EU (e.g. best practices).

[3] The argument is developed in Mendes, *Administrative Law Beyond the States: Participation at the Intersection of Legal Systems* (n. 1, above), pp. 111-132 and in Mendes, *EU law and global regulatory regimes* (n. 1, above).

decisions.[4] This may occur as a result not only of arguably imperfect formal rules of reception, but also of informal links of administrative collaboration established between EU institutions and bodies, on the one hand, and inter- and transnational regulatory bodies or networks, on the other.[5]

This paper focuses on procedural standards of participation to argue that their depletion by effect of reception can constitute a challenge to the premise that public authority ought to be structured and constrained by law.[6] Reception depletes the capacity of procedural standards to structure discretion and thereby constrain the exercise of public authority in areas of regulation where courts hardly enter. It potentially leads to situations of unrestrained authority. This perspective unfolds the deeper impact of reception of inter- and trans-national decisions on law's capacity to limit the executive. By relying on the external ramifications of its internal regulatory activity, the latter loosens the procedural constraints that would otherwise apply to its decision-making procedures.[7] The depletion of procedural standards therefore emerges as a problem of the rule of law, as it limits the law's ability to structure the exercise of discretion and constrain public authority. Behind complex governance arrangements that articulate EU and international actors and their decisions, what may be at stake is the balance between the exercise of authority, on the one hand, and the protection of autonomy, on the other, on which public law mechanisms have been built within the state. The analysis has an undeniable EU focus. Its starting point are the effects that the interaction between the EU and other regulatory systems has on EU (domestic) procedural standards.[8] Yet, as approached in this paper, this "internal perspective" points to the external and deeper dimension of the problem. What is being depleted are

[4] For more detail, see Mendes, *EU law and global regulatory regimes* (n. 1, above), Section 3. Highlighting the same problem for US decisions shaped by global regulatory norms and practices, Stewart (n. 1, above) at 702, pp. 705-709.

[5] Stressing the relevance of administrative incentives, in the case of the US, see Stewart (n. 1 above) pp. 705, 719, 747.

[6] Contrasting a governance and a public law perspective in the analysis of regulation beyond the state, Armin von Bogdandy et al., *Developing the Publicness of Public International Law: Towards a Legal Framework for Global Governance Activities* in THE EXERCISE OF PUBLIC AUTHORITY BY INTERNATIONAL INSTITUTIONS. ADVANCING INTERNATIONAL INSTITUTIONAL LAW (Armin von Bogdandy et al. eds., Springer, 2010) 3, pp. 7-16. Authority is used in this article as defined by Bogdandy et al., idem, pp. 11-12.

[7] Also indicating the problems of a sharp distinction between international and domestic affairs, from the perspective of the limitation of executive power, see Eyal Benvenisti, *Exit and Voice in the Age of Globalization* in 98 MICHIGAN LAW REVIEW 167, pp. 187-189 (1999), albeit referring to treaty-making powers.

[8] Mendes, *EU law and global regulatory regimes* (n. 1, above).

not rules or practices that assume a specific form in domestic legal systems, but the premise that law ought to structure and constrain the exercise of authority, irrespective of whether it results from internal or external action. This leads one to question the very legitimacy of inter- and trans-national decision-making procedures, even if through the lens of the values upheld in the domestic legal systems.[9]

Framing the depletion of procedural standards that ensure participation in decision-making procedures as a rule of law problem raises a number of conceptual and normative issues, which this paper addresses. To begin with, the association of this phenomenon with the rule of law is prone to criticism for two main reasons. First, the legal character of the procedural standards at stake is disputed. The use of the term "standard" connotes the idea that the rules or practices that support participation in decision-making procedures at the global level do not pertain strictly to law.[10] As they are practiced within the EU and within inter- and transnational regulatory regimes, they belong to the language code of governance and are far from being affiliated with the rule of law. Indeed, often these standards were put into place to enable public authorities to benefit from the knowledge of stakeholders, to create motivation for compliance, as a means of adjusting to claims of legitimacy.[11] Second, in the examples referred in this paper, these standards apply to procedures that lead to the adoption of regulatory decisions of general scope. Natural and legal persons are affected only indirectly insofar as such decisions bind or commit their authors and other decision-makers. The focus of the paper is not due process guarantees depleted when the chain of intertwined decisions results in the exercise of direct authority over individuals impairing their fundamental rights, which would speak directly to the rule of law.[12]

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[9] On the multifaceted concept of legitimacy, see Black, *Constructing and contesting legitimacy...*, (n. 11, above), in particular pp. 144-150. Acknowledging the limits of adopting a legal perspective on legitimacy, this paper sets out to assess the extent to which internationalised decision-making procedures can be captured by law.

[10] On a similar use of the term – opposing it to "principles" and "rights" – see Carol Harlow, *Global Administrative Law. The Quest for Principles and Values*, 17 EUROPEAN JOURNAL OF INTERNATIONAL LAW 187, at p. 190 (2006).

[11] Julia Black, *Constructing and contesting legitimacy and accountability in polycentric regulatory regimes*, 2 REGULATION AND GOVERNANCE 137, at pp. 144-151 (2008).

[12] The prominent example would be the reception in EU law of the UN Security Council resolutions establishing terrorist sanctions. That due process guarantees are an aspect of the rule of law is a common law perspective; it is however not unknown in the German conception of *Rechtstaat* and in the French construction of *État de droit* (see. e.g. Jacques Chevallier, L'ÉTAT DU DROIT, (Montchrestien, 5th ed., 2010) pp. 14-16, 19, 30, 51-52.

Next, once established that treating the depletion of procedural standards as a rule of law problem is conceptually possible, this approach has normative consequences. Procedural standards ought to retain the capacity of procedural law to structure discretion and constrain the exercise of public authority, which results from the intertwinement of decisions that cross different legal and regulatory systems. This approach will require adjustments and variations to the procedural rules currently practiced. Finally, this capacity also requires a reconceptualisation of the procedures through which such intertwinement operates, or at least of the external role of the actors involved. Instances of public authority emerge from the external links between procedures. Internationalised procedures result from processes of internationalisation (broadly understood as encompassing transnational regulation) and are neither only European, national nor international.[13] They result from a cascade of intertwined decisions. For this reason, they ought not be seen in segmented terms, at the risk of impeding solutions that constrain such authority.

The argument that the depletion of procedural standards of participation can be a rule of law problem is developed in the first part of the paper. The paper begins by returning to the empirical analysis on which it is based in order to assess the extent to which internationalised decision-making procedures may lead to instances of unrestrained authority (Section 2). Unrestrained authority, if it is possible to establish it, refers only to the formation of decisions. Therefore, the paper addresses only one of several ways in which discretion can be structured and authority constrained. Also in Section 2, the paper crucially moves on to clarify the conceptual, methodological and normative premises that enable us to read the depletion of procedural standards of participation in the light of the rule of law. This is the starting point of a more detailed conceptual and normative analysis that establishes the basis to bridge the two terms of a *prima facie* odd equation – participation and rule of law – and indicates the reasons why they ought to be bridged (Section 3). The second part of the paper outlines the normative consequences of reading the depletion of procedural standards as a rule of law problem. It argues that governance practices might need to be re-interpreted in legal

[13] Delmas-Marty, *Governance and the rule of law* in DEMOCRATIC GOVERNANCE. A NEW PARADIGM FOR DEVELOPMENT? (Séverine Bellina, Hervé Magro, Violaine de Villemur eds., Hurst & Co, 2009) pp. 207-216, at p. 208.

terms, revealing also the limits of current EU procedures. In addition, it argues that, to the extent that the exercise of authority stemming from intertwined EU and international procedures is to be brought under the realm of law, the respective procedures need to be reconceptualised. The paper suggests two possible routes: conceptualise them as composite procedures; emphasise the procedural duties of the EU institutions and bodies when acting in an external role (Section 4).

2. Framing the problem: A challenge to the rule of law

2.1. Two instances of depletion

Unrestrained public authority may occur insofar as international decisions received in the EU legal order are not subject to procedural constraints that would apply should such decisions be adopted internally, while by effect of reception they acquire the legal force that equivalent EU acts would have.[14] Let us start by revisiting two examples on which this argument is built in order to better assess the contours of the problem.[15] They refer to limit situations where the legal character of the procedural rules depleted and/or of the decisions finally adopted can be questioned. But in both cases the constraining effect of reception may have an indirect impact on the legal sphere of individuals.

The EU is member of the International Convention for the Conservation of Atlantic Tunas, and, as such, legally bound by the decisions of the respective Commission (ICCAT), among which fisheries conservation and management measures.[16] Such measures – for example, recommendations regarding the definition of total allowable catches of Bluefin tuna – are incorporated in EU law via Council Regulations adopted on the basis of Article 43(3) of the Treaty on the Functioning of the European Union (TFEU).[17] These are decisions that are at the core of the EU Common Fisheries Policy.

[14] As mentioned, the following analysis zooms in decision-making procedures and, specifically, rules and practices of participation, ignoring other possible mechanisms of control.
[15] The examples are taken from Mendes, *EU law and global regulatory regimes* (n. 1, above), where more detail is given.
[16] Article VIII(1)(a), (2) and (3) of the International Convention for the Conservation of Atlantic Tunas (available at http://www.iccat.es/Documents/Commission/BasicTexts.pdf, (accessed May 10, 2013). See, generally, Communication from the Commission "Community participation in Regional Fisheries Organizations (RFOs), COM (1999) 613 final Brussels, 8.12.1999, pp. 6-9.
[17] For example, Annex ID of Council Regulation (EU) No 40/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available in EU waters and, to EU vessels, in certain non-EU waters for certain fish

They have far-reaching impacts on the range of legally protected interests that ought to be protected and pursued in its implementation.[18] Equivalent EU acts that do not stem from international obligations are subject to consultation of Regional Advisory Councils, composed of interest representatives.[19] By legal determination, the Council needs to take their views into account when pursuing the public interests protected by EU fisheries legislation.[20] Consultation is explicitly excluded in the case of regulations that transpose decisions of Regional Fisheries Organizations, such as the ICCAT, and it is not compensated by the possibilities of participation of interest representatives in ICCAT decision-making procedures.[21] At least until recently, ICCAT's were mostly closed meetings, and NGOs had difficulties in accessing information.[22] The absence of procedural constraints at the international level leads then to a closed decision-making procedure. In addition, this procedure is not subject to a requirement of consideration of, or justification towards, the range of legally protected interests, which would apply if the decision would be adopted internally.

The European Commission and the European Medicines Agency (EMA) are part of a transnational network – the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) – that gathers also representatives of the Japanese and the American regulatory agencies for pharmaceuticals, as well as private associations representing the pharmaceutical

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stocks and groups of fish stocks which are subject to international negotiations or agreements (OJ L 23/54, 25.1.2013). Another type of measures are recovery plans – see, for example, Council Regulation (EC) No 302/2009 of 6 April 2009 concerning a multiannual recovery plan for bluefin tuna in the eastern Atlantic and Mediterranean, amending Regulation (EC) No 43/2009 and repealing Regulation (EC) No 1559/2007 (OJ L 96/1, 15.4.2009).

[18] Article 2(1) of Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy, as amended (OJ L 358/59, 31.12.2002), currently under reform (see Proposal for a Regulation of the European Parliament and of the Council on the Common Fisheries Policy COM (2011) 425 final, Brussels, 13.7.2011, and http://ec.europa.eu/fisheries/reform/ (accessed May 10, 2013).

[19] At present, these representatives come mainly from the industrial fishing sector, but the on-going reform of the Common Fisheries Policy envisages modifications also in this respect, with a view to ensuring a balanced representation of all interests involved (Article 52(1) of the Proposal cited n. above).

[20] Article 4(2) of Council Regulation (EC) No 2371/2002 (n. 18, above). On the role of Regional Advisory Councils, see Mendes, *EU law and global regulatory regimes* (n. 1, above), pp. 997-9.

[21] See Mendes, *EU law and global regulatory regimes* (n. 1, above), pp. 1000-4.

[22] G.D. Hurry, M. Hayashi, J.J. Maguire, "Report of the Independent Review", September 2008, pp. 29, 71, and recommendation 50 (available at http://www.iccat.int/Documents/Meetings/Docs/Comm/PLE-106-ENG.pdf, accessed May 10, 2013).

industry in these three regions.[23] The ICH guidelines define the technical requirements that ensure the safety, efficacy and quality of new pharmaceutical products (e.g. requirements regarding clinical trials in humans, the use of animal testing, the assessment of new drug applications). They are non-binding guidelines. They are received in EU law as non-binding guidelines of the Committee for Medicinal Products for Human Use (CHMP, operating within the EMA), but are used by the EMA as benchmarks against which to assess the quality, safety and efficacy of pharmaceutical products,[24] which is a condition *sine qua non* to obtain an authorization to market a new drug within the EU.[25] Alternative routes to comply with this requirement "may be taken" but need to be "appropriately justified".[26] ICH guidelines are adopted following a consultation procedure that, albeit conducted by EMA, does not provide any guarantees of due consideration of the views voiced, unlike the equivalent procedures followed for the adoption of purely EMA guidelines.[27]

In this last example, an additional aspect is relevant. Even though the weight of the pharmaceutical industry in consultation procedures for the adoption of internal guidelines is likely strong, the EMA purports to involve representatives of patients,

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[23] For more detail, see Ayelet Berman, *Informal International Lawmaking in Medical Products Regulation* in INFORMAL INTERNATIONAL LAWMAKING: CASE STUDIES, (Ayelet et al eds., TOAEP Academic Epublisher, 2012) 355-369 (available at http://www.fichl.org/fileadmin/fichl/documents/LOTFS/LOTFS_3_Web.pdf, accessed May 10, 2013).

[24] See, further, Mendes, *Administrative Law Beyond the State: Participation at the Intersection of Legal Systems*, (n. 1, above), 111-132, at p. 128 (also in Mendes, *EU law and global regulatory regimes* (n. 1, above), p. 1012).

[25] Article 12 of Regulation (EC) No 726/2004, of the European Parliament and of the Council, of 31 March 2004, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (O.J. L 136/1, 30.4.2004), as amended. See also Article 26 of Directive 2001/83/EC, of the European Parliament and of the Council, of 6 November 2001, on the Community code relating to medicinal products for human use (O.J. L 311/67, 28.11.2001), as amended.

[26] European Medicines Agency (EMA), "Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework", London, 18 March 2009 Doc.Ref. EMEA/P/24143/2004 REV. 1 corr, p. 5 (2.1 and 2.2).

[27] See further, Mendes, *EU law and global regulatory regimes* (n. 1, above), p. 1013. EMA, "Procedure for European Union Guidelines", (n. 26, above), p. 13. Unlike the EMA's usual practices of consultation, the ICH expert working group does not disclose the justification for accepting or rejecting the comments received. This is however crucial to ensure the effectiveness of consultation. Unlike the EU procedures for the adoption of ICH guidelines, US administrative procedure seem to give equivalent guarantees of participation in ICH guidelines and in the internal guidelines of the US Food and Drug Administration – see Ayelet Berman (2012), "The Role of Domestic Administrative Law in the Accountability of Transnational Regulatory Networks: The Case of the ICH", IRPA GAL Working Paper, 2012/1, pp. 23-28 (available at http://www.irpa.eu/gal-section/6566/ayelet-berman-the-role-of-domestic-administrative-law-in-the-accountability-of-transnational-regulatory-networks-the-case-of-the-ich-irpa-working-papers/, accessed May 10, 2013).

consumers and health care professionals in its consultation procedures.[28] In particular, by force of EU law, the interests of patients need to be protected in the decision-making procedures that lead to granting an authorization to market a new drug.[29] The EMA is bound by this requirement. This is not an explicit condition that ICH needs to comply with, which may influence the assessment of the views submitted by these groups where they actually participate in consultation procedures, fading their voice even more.[30] Crucially, in internal procedures, the pharmaceutical industry does not have a formal say in the adoption of internal guidelines, whereas it does in the adoption of ICH guidelines. This feature may raise doubts regarding the possibility of capture.[31]

The reception of ICH guidelines seems to pose more serious problems than the reception of decisions of ICCAT regarding the allocation of fishing opportunities, mentioned above. The problem is not only that the internationalised procedure gives fewer guarantees of participation. The problem is also that there are no procedural guarantees that the public interests that the EMA is bound to comply with by force of EU legislation are effectively considered in the adoption of the ICH guidelines that are incorporated in EU law. Although the purposes of the ICH are not incompatible with those interests – technical harmonization may even have an important role in fostering them – its activity is driven by commercial needs.[32] The risk that ICH guidelines may deviate from the public interests protected by EU pharmaceutical legislation may be enhanced by the possibility that embeddedness in transnational networks may increase the autonomy of EMA vis-à-vis the Commission and the Member States, as recent research suggests.[33]

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[28] EMA Procedural Guidelines (n. 29, above), 16 (4.6). More generally, see "The EMA Transparency Policy. Draft for Public Consultation" (Doc Ref. EMEA/232037/2009 – rev), London, 19 June 2009, namely p. 10, available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500005269.pdf (accessed May 10, 2013).

[29] Article 3(2)(b) of Regulation (EC) No 726/2004, (n. 25, above).

[30] A point also made in Mendes, *EU law and global regulatory regimes* (n. 1, above), p. 1013.

[31] On this point, see Berman, (n. 27, above), p. 27.

[32] It mainly aims at "reducing or obviating duplication of testing carried out during the research and development of new human medicines" (ICH Terms of Reference (2000), available at http://www.ich.org/about/vision.html, accessed May 10, 2013). See also Berman, *Informal International Lawmaking*, (n. 23, above), p. 357.

[33] Martijn Groenleer, *Linking up levels of governance: agencies of the European Union and their interaction with international institutions* in THE INFLUENCE OF INTERNATIONAL INSTITUTIONS ON THE EUROPEAN UNION. WHEN MULTILATERALISM HITS BRUSSELS (Oriol Costa and Knud-Erik Joergensen eds.,

2.2. Unrestrained public authority?

May these situations lead to possible instances of unrestrained authority? This case needs to be made with care. First, what results from the above is that international decisions may not be subject to procedural guarantees of participation that structure equivalent decision-making procedures in the EU. Per se, this does not necessarily entail a judgment regarding the exercise of authority. It may be debatable whether these decision-makers are vested with public authority and whether their determinations have legal value or nature (e.g. the authority of the ICH guidelines comes from the fact that an international expert forum, composed of regulators and industry, enacts them as best practices).[34] Secondly, this also does not entail a judgment regarding the adequacy of the procedures followed for their adoption. These procedures may be adequate for the type of decisions adopted at the international level and to the purposes served by the bodies that adopt them. It is also arguable that, irrespective of the level at which they are made, some of these decisions may be better left to the technical or political process, outside of the legal or quasi-legal realm. Certainly, in their origin and design, some of them were not conceived as legal processes at all.

Yet, irrespective of their source, legal or non-legal character, binding or non-binding nature, the international decisions mentioned are received as authoritative in the legal systems that implement them, and may acquire a legal and constraining significance by effect of such reception.[35] As such, they are capable both of constraining the legal sphere of the persons concerned by decisions adopted on their basis (e.g. pharmaceutical industries that, being excluded from the decision-making circles, are affected by a potentially detrimental rule), albeit indirectly; and of defining the composition of competing interests that, according to national or regional legislation valid in the systems where they are received, need to be respected in carrying out a given

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Palgrave Macmillan, 2012) pp. 135-54. It should be noted that the author explicitly says that his is a tentative conclusion in need of confirmation by further empirical research.

[34] See, further, Bogdandy at al (n. 6 above) pp. 14-16. Concretely on these examples, Mendes, *EU law and global regulatory regimes* (n. 1, above).

[35] For example, the ICH guidelines become the rules against which the quality, safety or adequacy of a medicinal product is assessed – an assessment that is a condition to grant a market authorization. See Article 12(1) Regulation 726/2004 (n. 25, above) and European Medicines Agency (EMA), (n. 26, above) (henceforth "EMA Procedural Guidelines") 4 and 5 (2.1 and 2.2).

policy (e.g. protection of health via a medicinal product that constitutes a significant therapeutic, scientific or technical innovation, the interests of patients, animal health).[36]

Whether binding or non-binding, such decisions acquire legal authority from the moment in which non-compliance or compliance has legal consequences – such as the refusal of a market authorization, or a heavier onus of proof regarding certain characteristics of a product, in the case of non-compliance with ICH guidelines; or prohibitions of fishing certain species as a result of ICCAT recommendations. This typically occurs at the domestic level, through reception. Even if more "imperfect" or no rule of participation may be adequate in the setting where these decisions are adopted, such rules or practices do not take into account the later vertical effect of the decisions adopted, i.e., the effective regulatory effects such decisions end up acquiring by effect of reception. Arguably, for this reason, the procedural rules and practices followed at the international level are not adequate to decisions that end up being legal in character, as much as internal rules and practices may not be.[37]

This is only part of the problem. The possibility of unrestrained authority does not result in isolation from the decisions adopted in inter- and trans-national regulatory fora, even though, when substantive regulatory decisions move up, the decision-making procedures through which they are adopted provide fewer legal guarantees against biases that may serve interests different from those that, internally, bind the decision-makers by virtue of law. The possibility of unrestrained authority results from the *combination* of lack of constraints in the law-making power of inter- and trans-national bureaucracies that would be adequate to decisions intended to become eventually binding on natural and legal persons, *and* from the side-stepping of procedural constraints to which domestic administrative decision-makers would need to abide if that decision would be adopted internally.

Irrespective of how they are formed and received, such decisions could *a posteriori* be subject to judicial review by EU and domestic courts (in the absence of apposite instances of review at the international level). Yet, not only is there little evidence so far

[36] Article 3(2)(b) Regulation 726/2004 (n. 26, above).
[37] Criticising the absence of procedural rights of participation in rulemaking procedures within the EU, see Joana Mendes, PARTICIPATION IN EU RULE-MAKING. A RIGHTS-BASED APPROACH, pp. 99–100 (Oxford University Press, 2011), Chapter 5.

of such controls being made,[38] but also many of the regulatory decisions adopted in this fashion hardly ever reach the courts. The EU and domestic courts tend to limit their assessment to the domestic act that incorporated the international decision with little consideration for its international links.[39] This would point to the need to include such controls *during* decision-making procedures, with a view to avoiding the possible absence of legal limits to the exercise of authority that ends up impacting on rights and legally protected interests of natural and legal persons. These are both individual or collective interests (e.g. smaller pharmaceutical companies producing generic medicines that cannot comply with the costly standards on the quality of pharmaceuticals that ICH has decided upon),[40] and diffuse interests (e.g. the interests of patients in the marketing of pharmaceutical products; the environmental interests in the definition of fishing quotas).[41]

2.3. Participation and law: premises

The examples mentioned refer to procedural standards of participation in decision-making procedures that involve the reception in the EU legal order of inter- and trans-national decisions. While analysing the possibility and contours of administrative law beyond the state, some authors hesitantly include the principle of participation under the heading of the rule of law, as one of its components.[42] Others consider it a "fashionable 'good governance' value" partially derived from managerial theories of public administration, rather than a classical administrative law principle stemming from the rule of law doctrine, albeit acknowledging the "particularly ambiguous"

[38] Making this argument with regard to the US, see Stewart (n. 1, above). To the author's knowledge, there is no known study in EU law on this issue. An additional problem may be judicial deference towards the external action of the executive (see Benvenisti, n. 7, above, pp. 194-195).

[39] Judicial review tends to focus on EU legal acts that transposed international decisions, and not the decisions themselves – see Nikolaos Lavranos, DECISIONS OF INTERNATIONAL ORGANIZATIONS IN THE EUROPEAN AND DOMESTIC LEGAL ORDERS OF SELECTED EU MEMBER STATES, Chapter 3 (Europa Law Publishing, 2004), pp. 56–57.

[40] See Berman, (n. 27, above), p. 12, on the concerns raised by ICH guidelines.

[41] These considerations assume that the regulatory processes at issue ought not be left only to the political process, due to the constraining effect they end up having in the legal sphere of natural and legal persons. This premise may be discussed, and one should bear in mind that not all instances of regulation have a legal relevance of the type that would justify legal constraints.

[42] Sabino Cassese, *Administrative Law Without the State? The Challenge of Global Regulation*, 37 NEW YORK UNIVERSITY JOURNAL OF INTERNATIONAL LAW AND POLITICS (2005) 691 (see, however, p. 694, where the author enumerates the rule of law and the principle of participation separately).

character of participation.[43] Others still, in a similar vein, stress "the fluidity of principles" that circulate different fields in evolving contemporary law, which, at the same time, reveals the "openness of law to principles stemming from other disciplines", but also constitutes "a fertile ground for speculations regarding global administrative *law*".[44]

Indeed, the legal character of participation is far from being a given. Several studies have highlighted the importance of participation (but also of transparency and accountability) in providing forms of democratic or legal legitimation (depending on the analysis) to certain inter- and trans-national regulatory regimes in the absence of state-like controls of democratic government.[45] *But can procedural standards of participation be considered as part of law?* Or by attributing to participation the ability to structure and constrain the exercise of public authority one is just dressing as law a phenomenon that effectively pertains to administrative practices, at the risk of providing them a veil of legitimacy they would otherwise not have? These are core questions to the argument of this article. Two aspects matter decisively in framing the discussion: first, the perspective from which one approaches participation, which defines this concept for the purposes of the current analysis; secondly, the methodological stance and normative premise that underpin this paper. Both shape the two terms of the equation under analysis.

From a legal perspective, participation entails a set of procedural rules that ensure consideration and balancing of the interests affected by decision-making, and, as result, enhances the material justice of the decisions adopted. Material justice refers, in this context, to "the substantive quality of a decision that embodies a composition of interests which results from having taken in due consideration and having balanced the different public and private legally protected interests that the decision-maker is bound

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[43] Carol Harlow, "Global Administrative Law: The Quest for Principles and Values", 17 EUROPEAN JOURNAL OF INTERNATIONAL LAW 187, pp. 188, 193, 195 (2006).

[44] Daniel Mockle, *Le débat sur les principes et les fondements du droit administratif global*, 53 CAHIERS DE DROIT, 3-48 (2012), p. 31-2, emphasis added. See also Alexander Somek *The Concept of 'Law' in Global Administrative Law. A Reply to Benedict Kingsbury*, 20 EUROPEAN JOURNAL OF INTERNATIONAL LAW (2009), 985-995 at pp. 985-8; *Idem*, *Administration without Sovereignty*, in THE TWILIGHT OF CONSTITUTIONALISM, (Petra Dobner and Martin Loughlin eds., Oxford University Press, 2010) 267-288, at p. 273.

[45] The literature on this issue is vast, in particular within the Global Administrative Law project. See, *inter alia*, Cassese, (n. 42, above). Considering that this approach points more to a weberian type of legal-rational legitimation, see Mockle (n. 44, above), p. 15; Chevallier (n. 12, above), p. 64.

to take into account".[46] From this viewpoint, participation ought to be legally protected when such interests are themselves protected by the applicable law and, as such, need to be considered by the decision-maker in the balancing of options that precedes the adoption of a decision. If in a regulatory setting, such as the ones mentioned in the examples above, participation does not relate directly to the protection of rights for the lack of an adversarial-type situation, to be relevant from a legal point of view, it needs to relate to the protection of legally protected interests.[47] From this perspective, this justifies that participation is intrinsically linked with justification. It affords legal protection insofar as the decision-maker is required to reason its decisions, not to a specific group of interest representatives, not to the network of peers by simply referring to the decisions they approved, but in the light of the law and of the legally protected interests it is bound to pursue or to respect.[48] How far this understanding of participation matches the EU rules and practices of participation exemplified in the beginning of the paper will be discussed below.[49]

Informing the current analysis is the deeper normative concern with law's capacity to extend beyond its traditional realm as well as beyond national borders, beyond *inter-national* law.[50] The following analysis builds on the methodological premise that traditional categories of (state) public law ought to be revisited and, to the extent possible, reconceptualised, with a view to capture the instances of exercise of public authority and address them with legal tools.[51] Arguably, this path ultimately allows identifying the elements in these regulatory spaces that can be captured by traditional categories of (state) public law, which inevitably will suffer a process of transformation when travelling to political and institutional contexts different from the ones where they

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[46] Mendes, PARTICIPATION IN EU RULE-MAKING (n. 37, above), 17, footnote 39. See also, on the rationales of participation Chapter 2, Section 2.2, in particular p. 35.
[47] On the difficulties of ascertaining in a given situation whether a legally protected interest is protected or not, see Jerry Mashaw, *Administrative due process: The Quest for a Dignitary Theory*, 61 BOSTON UNIVERSITY LAW REVIEW, pp. 889-91 (1981).
[48] Although this risks strengthening the voice of only a few – see Benvenisti (n. 7, above), 171.
[49] Section 3.
[50] Peer Zumbansen, *Defining the space of transnational law. Legal theory, global governance, and legal pluralism*, 21 TRANSNATIONAL LAW & CONTEMPORARY PROBLEMS, 305-335 (2012).
[51] This is in line with Zumbansen who underlines that "domestic experiences with law are crucial points of orientation" (n. 50, above), p. 324. Although his analysis focuses on transnational law, this reasoning applies also within the state to alternative modes of law production. For a contrary view, denying that the "law beyond the state" perspective is capable of grasping "the essence of transnational governance processes", see Somek, (n. 44, above),p. 275 and pp. 279-80.

originated. The challenges posed by this premise are greater than what this paper can realistically address given its scope and purpose. Important questions will remain unanswered – namely, how to identify such elements, what to keep of the public law categories in the new regulatory contexts, and in which instances (admitting that not all processes of regulation occurring beyond the state will be able to be captured by law, or, at least, the advantages of doing so might not overcome the disadvantages).

This methodological standpoint is informed by a normative premise. Accepting that, at whichever level it is exercised, "public power stands in need of legitimation and limitation"[52], this paper proposes that some of the mechanisms that are already in place in inter- and transnational settings – set up to at least create the impression of a structured exercise of discretion and to lend a sense of legitimacy to the respective decisions – be re-interpreted in the light of the idea that the exercise of such authority ought to be constrained. This may require bringing those mechanisms into the purview of law, and, in turn, extending law – and possibly also the rule of law – into the realm of regulation and governance where it does not always sit comfortably. The purpose of this re-interpretation would be to address the tension between authority and autonomy, in the sense of respect for a private sphere of liberty and dignity, as it enfolds today outside state-like sites of law production and, in particular, in supra-, inter- and transnational spaces. Internationalised procedures, albeit resorting to alternative modes of regulation, and irrespective of their form, may ultimately put at stake the balance between the exercise of authority and the protection of liberty/dignity that has been at the core of public law instruments in the liberal constitutional state. This may occur to the extent that such processes risk leaving a wide purview of discretion in the hands of decision-makers, whose decisions are perceived as not affecting legally protected interests and as not having a perceptible legal effect in individual legal spheres.[53]

While these premises may bring us one step closer to establishing possible normative links between participation and the rule of law, they are still one step away from laying them down. Once established, those links will flesh out the role of

[52] Dieter Grimm, *The Achievement of Constitutionalism and its Prospects in a Changed World* in THE TWILIGHT OF CONSTITUTIONALISM? (n. 44 above) 3-22, at p. 16.

[53] Arguing that too much discretion is left in the hands of the executive when acting in its international role and on other consequences of leaving the external action of the executive unbounded, see Benvenisti (n. 7, above), in particular 184-201.

procedural standards of participation as a means of structuring and constraining the exercise of authority and, specifically, of subjecting administrative actors to the laws that bind them when acting beyond the borders of their domestic jurisdictions.

3. The rule of law: does participation fit?

3.1. Rule of law…

The rule of law is a dynamic concept,[54] "a contingent legal theory".[55] In a late modern sense, it is the product of the legal-liberal traditions shaped in the political and institutional history of Britain, Germany, France and the US (namely, by the different conceptions of the State predominant in these countries in the 19th and early 20th centuries). Inevitably, the content of the rule of law is far from uniform and disagreement "extends to its core".[56] Each political context produced distinct political and doctrinal meanings and specific implications.[57] In one reading, the rule of law conveys the limitation of power by law to avoid tyranny and potential abuses and misuses.[58] Insofar as it translates as subjecting the executive power to respecting the law, this notion is arguably common to the different conceptions of the rule of law that developed in the main public law traditions of modern Europe.[59] This same idea has also become progressively under strain since the second half of the 20th century.[60]

Several qualifications have been added to this core idea of limitation of power: in a liberal tradition, the limitation of authority is inseverable from the protection of individual liberties and rights;[61] inspired by social democracy, the limitation of authority

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[54] Chevallier (n. 12, above), 12, 140; Brian Tamanaha, ON THE RULE OF LAW: HISTORY, POLITICS, THEORY (Cambridge University Press, 2004) p. 5.
[55] Chevallier (n. 12, above), p. 9.
[56] Tamanaha, (n. 54, above), p. 3.
[57] Contrasting essentially the meaning of "État de droit" and "Rechstaat", see Chevallier (n. 12, above), 13-66. On different historical and theoretical constructions, but with a stronger emphasis on the Anglo-Saxon traditions, see Tamanaha (n. n. 54, above), Chapters 3 to 8.
[58] Tamanaha, (n. 54, above), pp. 114-5.
[59] Jean Rivero, (1957), "*L'Etat moderne peut-il être encore un état de droit?*", EXTRAIT DES ANNALES DE LA FACULTÉ DE DROIT DE LIÈGE, pp. 65-101, at 69, who also stresses that this basic idea can only be understood by reference to its historical manifestations, conceptual and normative implications. In particular, the meaning of 'law' has evolved, referring not only to '*la loi*', but also to '*le droit*', thereby, in a sense, returning to the pre-revolutionary meaning of law.
[60] Rivero, (n. 59, above), questioning and defending the ability of the rule of law to ensure control over the exercise of authority and the liberty of the '*administré*'; Paulo Otero, LEGALIDADE E ADMINISTRAÇÃO PÚBLICA. O SENTIDO DA VINCULAÇÃO ADMINISTRATIVA À JURIDICIDADE (Coimbra: Almedina, 2003), pp. 137-191, and Chapter 2 of Part II.
[61] Chevallier (n. 12, above), pp. 51-52; Tamanaha (n. n. 54, above), pp. 32-36.

under the rule of law serves the preservation of human dignity, justice, and democracy.[62] Liberal conceptions tend to convey a formal meaning of the rule of law – stressing generality, prospectivity, stability and clarity as qualities rules ought to have under the paradigm of the rule of law.[63] Substantive conceptions, which emerged more predominately in the period that followed Western totalitarian experiences, underline the values that inform the law and are usually associated with the interventionist role law acquired in the welfare state. Formal and substantive conceptions of the rule of law are, nevertheless, in a "symbiotic relationship".[64]

This highly concise overview of possible different meanings of the rule of law – unsatisfactory in many respects – inevitably falls short of heeding the richness of two centuries of both political and legal theoretical reflection and historical evolution. Including it in this paper has however the purpose of supporting one argument: the content of the rule of law, being disputed, is also malleable. Or, more precisely, the core idea of the rule of law pointed out above – the limitation of power to ensure certain values (be it freedom, dignity, justice or democracy) – while having manifold implications, also entails the potential of the rule of law to adjust to changing realities.[65]

One may still rightfully argue that the rule of law "flourished in a certain ideological ground, rooted in a certain social and political reality; deprived of this substrate, cut off from its references, [the theory of the rule of law] appears only as an empty shell, a formal frame and becomes itself 'in-significant'".[66] This is a sound observation, which advises against too hasty extensions of the concept and theory. Nevertheless, even if seen as "a fragment of a civilization", as a piece of an "ideological whole",[67] if kept purely within its historical state-centric context, the rule of law risks

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[62] Chevallier (n. 12, above), pp. 68, 87, 88-95.
[63] Tamanaha, (n. 54, above), pp. 119 and 96-97.
[64] David Dyzenhaus, *The rule of (administrative) law in international law*, 68 LAW AND CONTEMPORARY PROBLEMS, 127-166, p. 130 (2004). Underlining that the formal-substantive distinction should not be overstated, see Tamanaha, (n. 54, above), p. 92; Chevallier (n. 12, above), p. 68.
[65] Following a substantive conception of the rule of law, endorsed here, this argument needs to be qualified by an important normative caveat: the transformative capacity of the rule of law relies on the adaptability of its content, but this can neither deny the dignity of the human person nor the institutions and procedures that allow one to consider a society as democratic. See Rivero, (n. 59, above), 100-101. For a different view, see, *inter alia*, Joseph Raz *The Rule of Law and its Virtue*, 93 THE LAW QUARTERLY REVIEW, 194-211 (1977), who is critical of conceptions of the rule of law that make it "signify all the virtues of the state" (198).
[66] Chevallier (n. 12, above), p. 50, author's translation.
[67] Rivero (n. 59, above), p. 101, author's translation.

ignoring that the tension between authority, on the one hand, and autonomy that connotes a private sphere of liberty and dignity vis-à-vis the exercise of authority, on the other, has moved also to the transnational space, beyond the national and the international spheres (and, within them, to sites of authority different from the state). It risks being "nullified by the process of transformation of the state",[68] and by the internal and external diffusion of power. From this perspective, without denying the relevance of also maintaining the rule of law within its less disputed realm – as referring to certainty, predictability and publicity, an independent judiciary, due process of law in courts, and, by extension, in administrative adjudicatory procedures, and other core features[69] – one would rather stress the "evolving nature" of the rule of law and, on this premise, inquire into its capacity to frame more recent transformations of public authority.[70]

For current purposes, the inquiry into the possible transformations of the rule of law focuses on procedural standards of participation and on a procedural meaning of the rule of law – one that zooms in law-generating processes and how they are constructed when initiated in inter- and transnational settings. In itself, this focus may be contentious. Analysing law-generating processes rather than law-applying processes from the perspective of the rule of law may be criticised on the ground that the rule of law is not about the making of the law, but about its qualities and, if at all about process, then about processes of law application.[71] Yet, in the type of situations exemplified in the beginning of the paper, the actors involved are at the same time law-makers and law-appliers and, in the former process, they condition the choices they follow in the latter.

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[68] Chevallier (n. 12, above), p. 12. As mentioned, while the paper focuses on internationalised administrative procedures, this reasoning also applies to transformations of public authority within the state (see n. 51, above).

[69] See the lists drawn by Lon Fuller, THE MORALITY OF LAW (Yale University Press, 1964), Chapter 2; Raz, (n. 65 above), pp. 198-202.

[70] Similarly, albeit drawing different implications from the argument, see Palombella, who stresses: "the ideal of the rule of law might also require different incarnations that are better suited to realising its normative rationale against a background of changing social settings" (Gianluigi Pallombella, *The Rule of Law and its Core*, in RELOCATING THE RULE OF LAW (Gianluigi Palombella and Neil Walker, eds., Hart Publishing, 2009) 17-42, pp. 39-40).

[71] Jeremy Waldron, *The rule of law and the importance of procedure* in GETTING TO THE RULE OF LAW, (James E. Fleming ed., New York University Press, 2011) 3-31, pp. 7-12, highlighting that a procedural conception is not part of the work of Hayek, Fuller, and Dicey. Waldron defends a procedural conception of the rule of law but he has in mind courts as law-appliers. On the implications of subjecting legislators to constraining laws, see Waldron, *idem*, pp. 24-25. This paper is concerned with law-generating processes that take place in settings where parliaments do not participate with decision-making powers, and, therefore, does not intend to engage in the debate on the ultimate origin of the legal norms that constrains public powers (see also Chevallier, n. 12, above, pp. 33-41, 48-50).

In addition, given the looser constraints of internationalised procedures, the limited judicial purview over the links between internal and external procedures and the virtual absence of public scrutiny of external regulatory activities, executive actors defining regulatory acts at the inter- and transnational level may more easily take biased decisions that have nonetheless a significant impact on internal law and on natural and legal persons.[72]

3.2. …and participation

The two poles mentioned – a procedural conception of the rule of law and participation – can be bridged by focusing on one of the core procedural principles of the rule of law (core, at least, in the common law world, but also, by English influence, in EU law): no one should be subject to a penalty or a serious loss resulting from unilateral public action without being given the opportunity to put forth their views on the facts adduced and legal norms relevant to the case. There are two distinct perspectives on this principle. From one point of view, its only translation in administrative-type procedures is the right to be heard and its ancillary rights. As a guarantee of adjudicatory procedures, the right to be heard is pertinent outside the courtroom only when the application of the law to a particular situation implies the adoption of a measure that can have adverse effects in the legal sphere of its addressees (typically, a sanction or a measure having a similar effect). Therefore, this principle is totally alien to the empirical reality that grounds the present normative analysis. This position is defensible. It has the support of administrative laws in many EU countries, where as a matter of principle, and despite the extensions in its scope of application, the right to be heard does not apply to procedures leading to the adoption of general acts.[73] If coupled with a so-called "thin conception" of the rule of law, such as the one defended by Raz, this view closes definitively the path this article proposes to explore (i.e. the possibility of reading participation in the light of the rule of law). When applied to the examples mentioned in the beginning of this paper, the proponents of this conception may likely argue that the

[72] See Benvenisti (n. 7, above), in particular pp. 171-175.
[73] Mendes, PARTICIPATION IN EU RULE-MAKING (n. 37, above), pp. 46-58.

rule of law is the rule of *the* law.[74] In one of the examples mentioned, there is hardly any law to account for (ICH rule-making is very thinly covered by legal rules);[75] in the other, the legal rules that are side-stepped by effect of reception of ICCAT recommendations enshrine duties of consultation of stakeholders created to compensate the shortcomings in the knowledge resources of policy-makers.[76] In addition, they would maintain that arguments for control of law-making by non-elected bodies have nothing to do with the rule of law.[77] Therefore, even admitting that a procedural conception of the rule of law could be defended, there is no way of linking it to the procedural standards of participation that form the object of the present analysis.

From another perspective, the principle mentioned above can be extended to cover participation in procedures leading to the adoption of general acts.[78] It does not translate merely into the right to be heard in adjudicatory procedures, but, arguably, it stresses more broadly "the value we place on government treating ordinary citizens with respect as active centers of intelligence",[79] irrespective of the form the action of public authority takes.[80] This is also in line with the idea of the person as bearer of fundamental rights: while subject to the exercise of public authority, the person must be treated in a way that respects him or her as a member of the collectivity and holder of rights.[81] Their dignity would be respected when the persons subject to authority are not treated merely as objects of decisions that interfere with their legal spheres. In this procedural reading, the rule of law "requires that public institutions sponsor and

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[74] According to Raz, "'the rule of law' means literally what it says: [t]he rule of the law" (n. 65, above), p. 196.

[75] In the case of the EU, only Article art. 57(1)(j) of Regulation No. 726/2004 (n. 25, above). From a formal perspective, the ICH and the EMA rules of procedure can hardly be considered "law".

[76] Recital 27 of Council Regulation No 2371/2002, (n. 18, above).

[77] Raz, (n. 65, above), p. 200.

[78] Mendes, PARTICIPATION IN EU RULE-MAKING (n. 37, above), pp. 58-70, 76-77, and 229-240.

[79] Waldron, (n. 71, above), p. 22. In this view, "law has a dignitarian aspect: it conceives of the people who live under it as bearers of reason and intelligence. They are thinkers who can grasp and grapple with the rationale of the way they are governed and relate it in complex but intelligible ways to their own view of the relationships between *their* actions and purposes and the action and purposes of the state" (Waldron, cit., p. 19, emphasis in the original). Again, when quoting Waldron, it is important to note that his procedural conception of the rule of law was not developed having in mind procedures that lead to the adoption of general acts.

[80] Mashaw points out that "as contemporary administrative acitivity (...) moves increasingly toward the use of generally applicable rules, a due process jurisprudence oriented to the protection of rights through adjudication, rather than toward the ways rights are created by quasi-legislative processes, appears impoverished" (Mashaw, n. 47 above, p. 896).

[81] Dyzenhaus (n. 64, above), p. 135. This is different from necessarily associating the rule of law with respect for fundamental rights.

facilitate reasoned argument in public affairs".[82] Respect for dignity requires an opportunity for argumentation.[83] The freedom the rule of law protects is then a "positive freedom: active engagement in the administration of public affairs, the freedom to participate actively and argumentatively in the way one is governed".[84] Arguably, pursuing it requires the subjection of public authority to legal rules that structure its exercise accordingly. In constraining decision-makers to engage with those who bear the effects of their decisions, these rules can ensure due consideration for the (individual, collective and diffuse) legally protected interests affected by public policy.[85] They thereby force decision-makers to consider the views voiced, to the extent that they are relevant to the interests legally protected, and, thereby, create the conditions to protect the dignity of those affected (in the sense mentioned above) and the material justice of public acts. Procedural rules ought then be connected to substantive legally protected interests.[86] This is one conception on the basis of which different rules can be set up, depending on the constraining character of the acts adopted (which needs to be determined taking into account the regulatory cycle in which they are produced), on the type of power being exercised, on the normative desirability and effective possibility of introducing legal rules in a given regulatory forum, on the trade offs that such rules could have.

Implicit in this procedural conception of the rule of law is the idea that procedural rules need at least to be considered in the creation of regulatory regimes, even if at the end they may not be introduced because the possible disadvantages are likely to overcome the advantages. Participatory procedures might not be beneficial in every

[82] Waldron, (n. 71, above), p. 19.
[83] Waldron, (n. 71, above), p. 20. Waldron's analysis focus on the tension between this strand of dignity and other strands of dignity associated to the rule of law that emphasise certainty and predictability (Waldron, n. 71, above, pp. 18-23). More broadly, on the values underlying a concern for dignity in the realm of public law procedures, see Mashaw, (n. 47, above), at p. 886, and on the challenges of a dignitarian perspective, *idem*, pp. 898-9.
[84] Waldron, (n. 71, above), p. 20.
[85] In a similar sense, Dyzenhaus (n. 64, above), pp. 129-130. For a critique of this way of conceiving the function of law, see West, *The Limits of Process* in Fleming, GETTING TO THE RULE OF LAW (n. 71 above) pp. 32-51, at 47-49 (to which one may counter-argue that a focus on the tension authority- liberty/dignity does not exhaust the function of law).
[86] See Section 1, on the legal meaning of participation.

circumstance.[87] Their risks and possible disadvantages are well-known. Among others, the juridification of participation introduces a different logic and purpose both in the mechanisms of participation and in regulatory processes. This entails risks that lawyers may not be able to heed but ought not ignore.[88] Risks of capture, in particular by powerful corporate actors, are often invoked. This effect is likely amplified in inter- and transnational settings where representation of diffuse interests (e.g. environment, consumer protection) is potentially weaker than nationally or locally, and institutional structures are looser than at the state level.[89] There are also risks of disruption of otherwise functional regulatory processes. Juridification of participation may be inadequate to the purposes that internationalised rulemaking serves, risking to block regulatory processes that rely specific ways of coordinating a variety of decisions and actors. They may thereby prevent the provision of collective goods.[90] In addition, procedures and their respective standards lend a sense of legitimacy to the exercise of authority that ultimately reinforces it.[91] They send "a message of fairness [and] of the futility of resistance",[92] instead of opening up possibilities of contestation and control, as defended above. Obstacles to practical feasibility, given the complexity of interests at stake and the multiplicity of potential participants; the difficulties in ensuring adequate links of representation within interest representatives; the lack of adequate enforcement mechanisms that would secure a well functioning procedure, are other critical points of participatory procedures. These risks and potential disadvantages advise against all-encompassing solutions and point to the need to strike "delicate balances" in specific regulatory contexts, taking into account the different realities to which procedures would apply.[93] They do not, however, constitute a principled objection to the introduction of procedural rules of participation capable of upholding the rule of law, in the sense indicated above.

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[87] Balancing the disadvantages of introducing procedural rules at the global level, but cautiously defending this option, see Giacinto della Cananea, *Procedural Due Process of Law Beyond the State*, in Bogdandy et al. THE EXERCISE OF PUBLIC AUTHORITY (n. 6 above) 965, at pp. 972-78.
[88] Chevallier (n. 12 above), p. 65.
[89] See Benvenisti (n. 7 above), who however argues that procedures can be a tool to reduce capture.
[90] On the latter argument, though with a different target, Nico Krisch, *Global Administrative Law and the Constitutional Ambition* in THE TWILIGHT OF CONSTITUTIONALISM? (n. 44 above), 245-267, at p. 252.
[91] Chevallier (n. 12 above), pp. 62-65.
[92] West, *The Limits of Process* (n. 85, above), p. 42, albeit referring to the procedural justice of trials.
[93] Benvenisti (n. 7 above), pp. 204-211.

Using the image of concentric circles, one is certainly closer to the rule of law – in the procedural sense indicated above – when the act originating in the inter- and trans-national sphere is an individualized determination, i.e. one the potential addressees of which, or affected persons, can easily be identified. It is this type of situations Waldron considered in his proposal for a procedural conception of the rule of law – the opportunity to make arguments about what the law is and ought to be in cases where authority has a direct bearing on the person. In his analysis, he specifically considers situations where the law is being administered in judicial procedures, although he does not exclude the possibility of such a procedural conception of the rule of law having broader application.[94] But, within certain conditions, the procedural conception of the rule of law proposed is capable of encompassing the participation of holders of rights and legally protected interests affected by general acts, that is, by law-making type of procedures.[95] These type of situations would then constitute an outer circle, where the exercise of authority does not have a direct bearing on individuals – an effect that will nevertheless occur via a follow up decision adopted elsewhere – but where the law is defined for more or less precise instances of regulation, with more or less detail regarding the specific entitlements and duties that emerge therefrom.[96] In between the core and the outer circle there may be potentially a great variety of situations.

In the outer circle, the possibility of harm being produced that may ultimately have a detrimental impact on individual legal spheres cannot be excluded. The lack of consideration, or a manifest disproportionate weighing of competing legally protected interests can lead to such an effect.[97] Issues of dignity can also be involved when decisions are adopted without due consideration of the interests concerned, which, by legal determination, ought to be balanced – and not only when rules are unclear, unstable, and retrospective.[98] Arguably, if accompanied by requirements of justification, participation in the adoption of this type of decisions would favour the balancing of

[94] Waldron, (n. 71, above), pp. 19, 24 and 26.
[95] For more detail, see Mendes PARTICIPATION IN EU RULE-MAKING (n. 37 above), pp. 61-70, 229-240.
[96] Similarly, Mendes, PARTICIPATION IN EU RULE-MAKING (n. 37 above), pp. 229-240
[97] Mendes, PARTICIPATION IN EU RULE-MAKING (n. 37 above), p. 369, drawing on José Joaquim Gomes Canotilho, *Relações jurídicas poligonais, ponderação ecológica de bens e controlo judicial preventivo*, REVISTA JURIDICA DO URBANISMO E AMBIENTE REVISTA JURÍDICA DO URBANISMO E AMBIENTE, n. 1, 55–65 (1994), p. 61.
[98] Mashaw, *Administrative due process* (n. 47, above), p. 897. But see also p. 898, on the challenges of a dignitarian perspective.

competing legally protected interests, and, in doing so, avoid compromising the material justice of the ensuing decisions.[99] While the opportunity of reasoned argumentation in shaping a rule or decision does not in itself guarantee this outcome, it creates the conditions to avoid biased, possibly self-interest, acts that deny material justice.

However, this is the point where the boundaries that could delimit a procedural conception of the rule of law, on the one hand, from a democracy argument that would ground the democratic legitimacy of decision-making on the search for the most adequate solution via an argumentative process, on the other, and also from participation as a governance principle, risks becoming blurred. At the same time, this is also the point from where on one can identify the situations in which the coordination between public and private actors that join efforts in decision-making procedures standing at the margins of law – or squarely falling outside its realm – should be subject to legal principles and rules inspired by a procedural conception of the rule of law.

3.3. Still rule of law?

Would the subjection to procedural rules that structure the exercise of authority in such situations still be part of the rule of law? Already in the late 1970s, Raz argued: "we have reached the stage in which no purist can claim that truth is on his side and blame the others of distorting the notion of the rule of law".[100] Participation can be, and is usually, defended on grounds different from the rule of law – transparency and participation of the public (democracy inspired argument), or as an instrument to achieve better regulatory outcomes that leaves the choices of participation fully in the hands of the decision-maker (governance). From a legal perspective, it is justified by the need to limit the exercise of authority due to the legal effects of the decisions adopted by a public authority.[101] Whether participation in the latter sense can be considered from a rule of law perspective, is debatable. One may argue that invoking the rule of law in this case may only amount to invoking the symbolic meaning of this principle. However, the above analysis shows that the purpose of making a rule of law claim is within the "rule of

[99] On material justice, see text accompanying n. 46, above. On the importance of reason giving from a dignitarian perspective, in addition to its instrumental value to political and legal accountability, see Mashaw *Reasoned Administration: The European Union, the United States, and the Project of Democratic Governance*, 76 GEORGE WASHINGTON LAW REVIEW 99 (2007), at pp. 115, 118.
[100] Raz (n. 65, above), p. 196.
[101] See Section 1 above.

law ethos", if this is perceived as encompassing the protection of the dignity of the person and the material justice of public acts, in the sense proposed. Participation can ensure that the persons affected by decisions of public authority (irrespective of their form) are treated in their autonomy as members of a collectivity and holders of rights, rather than as objects of decisions that are alien to them. Insofar as this is the case, participation is a legal tool to structure and constrain the exercise of authority.

Returning to the examples mentioned in the beginning of this paper, harm to legally protected interests that ultimately may have a detrimental impact on individual legal spheres can result from the regulatory cycles initiated by the adoption of ICH guidelines and of ICCAT recommendations. The procedures through which the initial decisions are adopted do not entail procedural guarantees that ensure the due consideration of the interests protected by the laws of the participating entities (in the case analysed, the EU). As mentioned, they are later applied in the domestic legal order as adopted in inter- and trans-national fora, via decisions that concretise their legal effect in the legal sphere of those concerned, which in turn are adopted through procedures that also do not entail such guarantees. As an effect of the reception of inter- and trans-national decisions, the holders of the legally protected interests concerned may suffer harm as a result of unilateral public action (in this case, intertwined decision-making adopted at different levels of governance) without being given the possibility of – via interest representatives – putting forth their views, and without procedural guarantees that the legally protected interests they hold have been balanced by the decision-makers. At stake are interests that are legally protected in the EU also in the form of fundamental rights, the pursuance of which is dependent on technical and scientific issues such as those decided via internationalised rulemaking procedures.[102] From an objective perspective – i.e. one that detaches from the individual situation of the persons affected - there is a dearth of procedural mechanisms that ensure that the discretion exercised via these regulatory processes is structured and authority constrained in a way that it complies with the law to which administrative entities are bound, while the legal effects of their decisions in legally protected interests are

[102] Articles 35 (insofar as it refers to a high level of human health protection) and 37 (environment). I am grateful to Gareth Davies for pointing this out.

potentially significant. Arguably, this result contradicts the values conveyed by the rule of law, as approached above.

It is this aspect – the capacity of procedural standards to structure discretion and constrain the exercise of authority – that risks being depleted by the effect of the interaction of legal regimes. One problem with this construction is that also within the EU the procedural standards that are depleted as a result of reception are not legal guarantees. What would be depleted then? At first sight, procedural standards of participation established in the realm of governance, outside legal parameters *stricto sensu*, that only due to a stretch of imagination could possibly be read with a rule of law lens. Nevertheless, the procedural rules that allow for participation in the decision-making procedures analysed *can have* the effect of structuring and, hence, limiting authority. Certainly, a concern for constraining authority is not the main reason why they were created in the first place.[103] However, the way they have developed – at least as far as this can be determined on the basis of written procedural rules enshrined in Commission Communications and agency's rules of procedure applicable in the cases mentioned – does not differ in essence from legally binding rules of notice and comment that would constrain the procedures to which they apply.[104] In this sense, they have at least the *capacity* of constraining the exercise of authority. This assertion neither means that they cannot be critically assessed in the light of this aim, improved to better ensure it, nor that this is actually the effect they have. On the contrary, it sheds a critical light also on the procedural rules followed within the EU. The difference between governance or administrative practices and legally binding procedures remains the origin of such rules and the consequences of non-compliance – voluntarily followed practices (self-constrain), in one case, externally determined legal rules that can be enforced via judicial review, in the other. Admittedly, not in all cases there are legal arguments to defend that the transition from one model to the other ought to be made.[105] At any rate, it is precisely this capacity that one cannot identify in the procedural rules that apply to decision-making procedures developed in the corresponding international and

[103] They are more adequately interpreted as following the line of governance reforms that still build on the 2001 White Paper of the Commission on Governance. See Mendes, *EU law and global regulatory regimes* (n. 1 above), pp. 997-999, 1011-1013.
[104] Mendes, *idem*, and PARTICIPATION IN EU RULE-MAKING (n. 37, above), p. 370.
[105] See the legal meaning of participation as characterised in Section 1 above.

transnational spaces analysed, to which substantive decisions are effectively transferred by effect of international agreements or international regulatory cooperation. They are weaker because, in one case, there is no legal determination according to which interest representatives should be consulted, and logically also no duty to take the views received into account, contrary to the EU procedural rules that would otherwise apply (fisheries); in the other case, there seems to be no concern regarding the feedback to be given to the participants neither public explanations on the options finally followed (medicines). The value of participation remains in the shade, since it is hardly possible for interested persons to assess how their contribution was treated, which in turn compromises the ability of the respective procedures to structure discretion and constrain the exercise of authority.

Procedural standards of participation (accompanied by guarantees of justification) may be as good as it gets in terms of structuring and constraining the exercise of authority in areas of regulation where the role of law is unclear, whether they include the reception of international and transnational decisions or not. At stake is the limitation of authority that is characteristic of a legal system that purports to obey to the rule of law and that is concerned with structuring the discretion of administrative decision-makers. What one then misses (what is depleted) is one of the mechanisms that constrain decision-makers to justify their decisions in the light of the public interests they are legally bound to pursue.

4. The transformative potential of a rule of law inspired perspective: reconceptualising decision-making procedures?

If the depletion of procedural standards of participation by effect of reception of decisions adopted within inter- and trans-national regulatory regimes can be perceived as a problem of rule of law, which consequences follow? Which adjustments and variations to the procedural rules that are practiced in transnational spaces would this perspective require? There are two different, but related aspects to this question. First, as implied above, approaching participation from the perspective of the rule of law requires reinterpreting processes and mechanisms that were introduced in decision-making with purposes that are far from an ideal of constraining authority or, even more so, from a concern of respecting "the freedom to participate actively and

argumentatively in the way one is governed", to use again Waldron's terms.[106] It requires reinterpreting them in legal terms, transforming current practices into rules that would limit public authority, therefore, creating legality (or quasi-legality) where thus far it has not existed. Indeed, the very reason for approaching participation from a rule of law inspired perspective is the subordination of the exercise of authority to law via procedural constrains of legal nature or via constraints that can be considered functionally equivalent, even if they remain formally different. Secondly, what would such a transformation imply in international and transnational settings? These two aspects point to two related consequences: a change in approaching the procedural standards that are currently in place, and a change in approaching the procedures where they apply.

The transformation of the procedural standards would occur along the lines indicated above. As argued, in instances where the exercise of public authority is at stake and, in addition, holders of the legally protected interests concerned may suffer harm as a result of unilateral public action, participation as a part of governance discourses and participation inspired by a rule of law perspective could and should be bridged. The decision-making procedure should entail guarantees that the decision-makers duly balance the legally protected interests concerned. These may be legal guarantees, sanctioned by law, or may stem from institutional practices that, nevertheless, have the capacity of constraining the exercise of authority through means other than the law. The precise shape of these guarantees would depend on a variety of factors.[107] Moreover, the advantages of their introduction would need to be balanced against their possible disadvantages in the concrete regulatory settings at issue.[108] That claim points to the need to, at least, preserve the procedural standards that are capable of structuring the decision-makers' discretion, and hence, of constraining the authority they exercise when adopting general acts – the ones depleted as an effect of reception of international decisions. But it also indicates that the EU procedures themselves ought to be re-thought in the light of this conception, with a view to ensuring that self-imposed

[106] Waldron, (n. 71, above), p. 20.
[107] See page 22 above.
[108] See Section 3, under "... and participation".

procedural rules may function as effective constraints, and do not merely coat decision-making with a veil of legitimacy.

This leads us to the second consequence mentioned. Advocating this transformation postulates also a new way of approaching procedures, for two reasons. First, the transformation of procedural standards is defended in the adoption of acts that, irrespective of their source or form, entail the exercise of public authority. In the cases analysed above, such instances can only be properly identified if one takes into account the external links of decision-making procedures. This point has been made above.[109] Second, if procedures continue to be viewed in segmented terms, i.e. only in their horizontal dimension, possible solutions to constraining the exercise of authority face considerable hurdles or are unsatisfactory, for the reasons explained next.

If one takes an horizontal view on internationalised procedures, separately analysing their global and domestic (in our case, European) levels, the normative perspective defended above would lead to one of three possible claims: first, procedural standards that structure the administrative discretion and, hence, limit the exercise of authority, need to be introduced in international and transnational law-making procedures (centralised solution); second, and alternatively, when pursuing international activities, EU bodies and institutions ought to be bound, internally, by the same procedural rules that apply when there are no instances of reception (decentralised solution); thirdly, both solutions need to be followed (combined solution).

The centralised solution raises one important objection: the procedures currently in place in those regulatory fora may be adequate to the type of decisions that are therein adopted. As mentioned above, the problem of unrestrained authority may only emerge from the vertical effects of these decisions. Therefore, one may argue that the problem lies only down the regulatory chain, hence, it is a problem of how these decisions are received – in other words, a problem of the domestic legal systems. If at all, changes would be needed there. Should one still agree that the procedural standards practiced in international and transnational fora should be changed, it would follow from the normative perspective defended above that such standards would need to be

[109] Section 2, under “unrestrained authority?”.

constructed in a highly complex way. They would need to accommodate the legally protected interests of the legal orders of the participating members, and consider the possible harmful effects of their decisions in third countries that suffer the effect of the decisions adopted. The potential complexity of this solution could block decision-making, rendering it ultimately both unfeasible and undesirable.

The decentralised solution would be the suitable alternative, given that the problem lies in the domestic legal orders. It is the legal orders where the depletion of procedural guarantees may be problematic that would need to adjust their mechanisms of reception. But this solution is equally unsatisfactory. First, the argument overlooks that the domestic legal systems are either legally bound by the substantive decisions adopted externally, or simply follow them for reasons of administrative convenience. Introducing procedural guarantees at the moment of reception would very likely be a window-dressing exercise, since it would be incapable of impacting in any way on substantive decisions already adopted elsewhere.[110] Alternatively, it would place the domestic authorities in a difficult position, since they would face the possibility of needing to refuse reception (on legal grounds) if this would mean a deviation from their own law. The latter option is unrealistic. Domestic authorities in charge of reception are often the same that have made the external decisions they then receive (which does not mean they will duly consider the legally protected interests they are bound to respect internally). Therefore, they will not be prone to setting aside the external decision, for procedural or substantive reasons. Domestic authorities will probably more easily use the argument that "unfiltered" reception (i.e. not subject to further internal procedural guarantees) is the result of their international duties, and compliance with the latter justifies that they do not follow procedures that would be practiced internally, as the example of reception of ICCAT decisions demonstrates.[111] The decentralised solution is unsatisfactory for a second, related reason. The insistence on a domestic – internal – perspective, if at all, can only solve problems of depletion of procedural guarantees within the domestic legal system (in our case, the EU). It only alerts to an internal

[110] Similarly, albeit referring to accountability for individual decisions, see Carol Harlow, "Composite Decision-making and Accountability Networks: Some Deductions from a Saga", JEAN MONNET WORKING PAPER 04/12, pp. 27-28 (2012).
[111] Mendes, Mendes, *EU law and global regulatory regimes* (n. 1, above) p. 1000.

problem of consistency,[112] in which case possible normative solutions following the views defended above would fail to address the problem of unrestrained authority in internationalised rulemaking. As pointed out, the challenge of creating adequate procedural guarantees may lay in the exit options that external regulatory fora provide, as the ICH example shows, or in the very approach of domestic authorities regarding their international role and obligations.

The combined solution is compromised by the fact that it would still rely on a multi-level approach, which, for the reasons stated above, is unsuitable to address the problem of unrestrained authority addressed in this paper. It does not escape the problems of the centralised and of the decentralised solution, namely because it would follow an horizontal-segmented perspective on the decision-making occurring at each level, and, thereby, it would likely overlook the fact that the actors involved in the different regulatory stages may be the same using with "different hats".

If decision-making procedures are in essence neither European nor international, as the examples show, international regulatory activities are then better perceived as a continuation of internal activities, and vice-versa,[113] rather than a separate, diplomatic-type or necessarily expert-dominated fora. This leads us to stress a point made above: one needs to focus on the functional inter-dependence of regulatory decisions adopted at the inter- or transnational level and at the EU level, and, therefore, search for the external links of decision-making procedures. Thinking of international regulatory cooperation from the perspective of the links between the different procedures that support it has the advantage of capturing the entirety of the regulatory chain that is triggered by decisions adopted in global regulatory fora and given effect at the regional and national levels. Focusing on their links, across legal systems, contributes to assessing the legal relevance of normative acts adopted at different levels of governance,

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[112] This can work in opposite directions (see Mendes, *EU law and global regulatory regimes,* n. 1 above, pp. 1003-4, 1008-9).

[113] Daniel Bethlehem, *International Law, European Community Law, National Law: Three Systems in Search of a Framework. Systemic Relativity in the Interaction of Law in the European Union* in INTERNATIONAL LAW ASPECTS OF THE EUROPEAN UNION, (Martti Koskenniemi ed., Kluwer Law International, 1998), 169-196, pp. 177, 194. See also, Sabino Cassese, *Administrative Law Without the State? The Challenge of Global Regulation*, (n. 1, above), 663, pp. 680-685. Armin von Bogdandy and Philip Dann, *International Composite Administration: Conceptualizating Multi-level and Network Aspects in the Exercise of International Public Authority*, in THE EXERCISE OF PUBLIC AUTHORITY BY INTERNATIONAL INSTITUTIONS. ADVANCING INTERNATIONAL INSTITUTIONAL LAW (von Bogdandy et al. eds., Springer, 2010), 883-912, p. 887.

the legal value of which may be questionable on formal legal grounds (e.g. informal legal acts may eventually be considered as preparatory acts of a final decision, adopted at a different regulatory level). This holistic view enables a better grasp of the reality of international or transnational regulation and a better perception of the problems involved, highlighting their effective impact on legally protected interests and, possibly, on the legal spheres of natural and legal persons. The decision-making procedures that operate the substantive coordination of the legal systems involved ought to be seen as segments of a broader regulatory cycle. This perspective may lead one to questioning whether domestic procedures are as autonomous as they appear to be when seen in isolation from those external links. Ultimately, this line of thought may lead to re-conceptualising decision-making procedures, with a view to ensuring that the exercise of public authority that results from international regulatory cooperation remains structured and constrained by law or by quasi-legal institutional practices that are functionally equivalent to legal procedural guarantees.[114]

4.1. Composite procedures

Highlighting the external links of decision-making procedures created by effect of international regulatory cooperation evokes composite administrative procedures.[115] Composite procedures involve decisions of different bodies or entities – that in the case of internationalised procedures are situated outside one legal system or regulatory regime – and therefore encompass one or more intertwined sub-procedures that are functional to the adoption of a final decision. The concept has been used in EU legal scholarship not only to describe the functional interdependences of decisions taken by different EU and national regulatory bodies, but also to highlight the problems of legal

[114] On the formal difference that remains despite this functional equivalence, see p. 27 above.

[115] The concept is related but not identical to "composite administration". Proposing this concept as an analytical tool to explain international cooperation, see Bogdandy and Dann, *International Composite Administration*, (n. 113, above), "Composite administration", as proposed by Bogdandy and Dann, focuses broadly on bureaucratic cooperation between international institutions and other legal entities of bureaucratic nature, including exchanges of information, irrespective of specific processes of decision-making (886, 892). "Composite administrative procedures" is a more limited concept (see the text that follows above). It can be seen as an instance of composite administration. Both concepts also have in common the fact that, beyond the State, they have been first conceptualised to explain administrative and procedural collaboration within the EU. Arguing that the terminology of "composite decision-making" extends to any situation of joined action between autonomous entities pursuing common public aims, see Harlow, *Composite Decision-making* (n. 110, above), p. 4.

protection arising from the allocation of such procedures to different jurisdictions.[116] The same concept may be useful to capture the reality of substantive regulation that depends on the confluence of decisions adopted at the inter- or transnational level and at the EU level. It may allow the interpreter to focus on the decisive moments of the definition of the content of regulatory acts, and, on this basis, redefine accordingly the role law should have in the respective regulatory cycle. For instance, when procedural rules are defined for the establishment of fishing quotas within the EU – whether policy-oriented or not – it can hardly be ignored that many of these measures may be pre-defined by Regional Fisheries Management Organizations (RFMOs) and only transposed into EU law, which ensures their legal effects. When total allowable catches are defined in RFMOs and transposed into EU law, they are not subject to the rules of participation functionally equivalent to those that apply to similar substantive decisions adopted purely within the EU.[117] Is such a situation normatively justified? Are the rules of procedure that guide decision-making of the RFMOs Fisheries Commissions designed with a view to structure the exercise of public authority in a way that complies with requirements of the rule of law that are valid within the legal orders of the RFMOs member states? Oughtn't they be in view of the vertical effects they produce? By approaching this instance of regulation from the angle of composite procedures, the interpreter is led to questioning the effects that international regulatory collaboration may have in legal guarantees valid within the legal systems that serve such collaboration. More importantly, focusing on the links between what may be segments of a broader regulatory cycle may lead, in some cases, to defending the juridification of the segments of the composite procedures where the substantive decisions are effectively shaped.[118]

Yet, using composite administrative procedures as an analytical tool may open more questions than it gives solutions. If the term is used as developed in EU administrative law literature, composite administrative procedures require, first, a legal

[116] See Giacinto della Cananea, *The European Union's mixed administrative proceedings*, 68 LAW AND CONTEMPORARY PROBLEMS 197-217 (2004) and Herwig Hofmann, *Composite decision making procedures in EU administrative law* in LEGAL CHALLENGES IN EU ADMINISTRATIVE LAW TOWARDS AN INTEGRATED ADMINISTRATION (Hofmann and Türk eds., Edward Elgar, 2009), 168-176.
[117] See, further, Mendes, *EU law and global regulatory regimes* (n. 1, above).
[118] A similar idea was defended, in a different context, in Mendes, PARTICIPATION IN EU RULEMAKING (n. 37, above), pp. 159-60.

connection on the basis of which one may establish that the coordination of different administrative actors is directed at one final outcome;[119] secondly, they require the lack of autonomy of the sub-procedures that compose them, due to their structural connectedness.[120] There is no necessity to transpose these two characteristics to a possible conceptualisation of composite procedures in the context of international cooperation.[121] "Composite procedures" is not an established legal term and using it in a different setting opens the way for different conceptualisations.[122] Nevertheless, they indicate the conceptual difficulty of analysing internationalised procedures as composite. In the context of international regulatory cooperation, what are the legal links on the basis of which a sufficient interdependence can be established? More importantly, would it be possible, on the basis of such links, to identify the moment (or moments) in which the content of the regulatory decisions is defined, and propose, accordingly, a re-definition of the procedural guarantees within the overall composite procedure? This latter question points to a normative difficulty: would composite administrative procedures be an effective tool in ensuring that the exercise of authority would be constrained by procedure? It should be reminded that in the EU's integrated administrative system, such procedures remain a challenge to legal protection. Legislative acts may design procedures that combine the regulatory decisions adopted by EU and national authorities, but the scope of procedural rules remains separate. The segments of composite administrative procedures developed at the national level are subject primarily to national rules of procedure, but also to EU law; those developed at the EU level are subject to EU rules of procedure.[123] Procedural rules that ensure

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[119] Cananea identifies this as the structural element that allows distinguishing what he terms "mixed administrative proceedings" managed by two or more administrations from "linked proceedings" that remain legally distinct (*idem*, p. 210). See also Massimo Giannini, 2 DRITTO AMMISTRATIVO, 2nd ed, 652-53 (1988). On the notion of administrative procedure, as requiring the production of one final outcome, Giannini, pp. 529-30.

[120] On the lack of autonomy of sub-procedures as a distinctive feature of composite administrative procedures, see Luis F. Maseo Seco (2004), *I procedimenti composti comunitari: riflessioni intorno alla problematica della impossibilità di difendersi ed eventuali alternative* in I PROCEDIMENTI AMMINISTRATIVI DELL'UNIONE EUROPEA. UN'INDAGINE. ATTI DEL CONVEGNO (*Studio, Urbino,* Giacinto Cananea and Matteo Gnes, eds, *2003)*, Torino: Giappichelli, pp. 11-32, at pp. 17-18, drawing on Parejo Alfonso *et al.*, 1 MANUAL DE DERECHO ADMINISTRATIVO (Barcelona, Ariel, 1998) 551-603 p. 559).

[121] I am grateful to Benedict Kingsbury for this point.

[122] See Bogdandy and Dann's analysis with regard to composite administration (n. 113, above).

[123] Jacques Ziller, *Exécution centralisée et execution partagée: Le fédéralisme d'exécution en droit de l'Union Européenne*, in L'EXECUTION DU DROIT DE L'UNION, ENTRE MECANISMES COMMUNAUTAIRES AND DROIT NATIONAUX, (Jacqueline Dutheil de la Rochère, ed., Bruylant, 2009) 111-138, at p. 127-8.

participation tend to fall through the mesh that supports the administrative collaboration between national and EU administrations.[124] In the international and transnational sphere, when considering interlinks between different legal systems and regulatory regimes outside integrated administrative structures, the possibility that constructing decision-making procedures as composite would have normative effects of the type envisaged here is even dimmer.

These difficulties and open questions do not deny per se the explanatory value of this approach. For the reasons indicated above, it can be a useful starting point to addressing the normative problems that emerge from internationalised procedures. Using the lens of composite procedures highlights that structuring and constraining the exercise of authority may "entail a complex structure, capable of functioning at various levels (...) of including all the relevant actors (...) and of organising various sub-sectors".[125] But it requires an analysis that cannot be further developed here.

4.2. Actors and their procedural duties

Another way of avoiding a level-segmented conception of procedural rules and their depletion is to focus on the actors involved in the regulatory cycle and on the legal and institutional requirements valid within their legal systems. The members of international or transnational regulatory fora, insofar as they represent public entities, are bound by formal and informal rules that shape their procedural behaviour and their substantive decisions. These are valid within their legal orders, but to the extent that their international regulatory functions are a continuation of their internal regulatory functions, such rules should also bind their external actions. Moving decision-making from one forum to another cannot *a priori* lead to sidestepping those rules. Focusing on the EU and on the examples used in this paper, EU representatives in Regional Fisheries Management Organizations, among other rules, are bound by the basic regulation that defines the legally protected interests and the governance principles valid in that field act within the EU Common Fisheries Policy. The EMA acting in its external role, when sitting in the ICH expert committee, is bound by the substantive requirements of the EU

[124] See, e.g. the procedure for the authorisation of novel foods in Joana Mendes PARTICIPATION IN EU RULE-MAKING, (n. 37, above), p. 334-341. See *idem*, pp. 159-160, on the drawbacks of a divided system for the effectiveness of the right to be heard.
[125] Delmas-Marty (n. 13, above), p. 208.

pharmaceutical law and should also by bound by rules of procedure it defined in order to respond to claims of legitimacy and accountability of its constituencies.[126] Focusing on the EU's responsibility as an external actor in the sense proposed, highlighting the need for consistency between its external action and its internal policies (in line with what is prescribed now in Article 21(3) TEU) would have both internal and external consequences.

External action ought to serve the purposes that were defined by EU law, and to the extent possible, comply with the conditions that, *internally*, ground the legitimacy of decision-making. Given the eventual domestic ramifications of the decisions the EU co-authors externally, deviations from internal substantive and procedural rules ought to be justified internally. EU decision-makers ought to demonstrate that the decisions adopted externally – or, at least, what the EU strove for in their adoption – do not contradict the content of the law by which they are bound. Deviations may of course be required by the very fact that these decision-makers are members of inter- and transnational regulatory fora. Also new issues not envisaged in the laws of the participating members are likely to arise. But their external decisions and actions should still be subsumed under the constitutional and legislative framework under which they operate. Justification, as proposed above, would ensure that link.

In addition, stressing the functional interconnectedness between these external decisions and the internal decisions of reception would create the conditions to identifying the situations in which the external decisions may have a detrimental effect to legally protected interests, through a regulatory chain of interwoven decisions. This may require the transformation of internal procedural standards, if not by adjusting the possibilities of participation accordingly, by strengthening the requirements of justification, which would need to take this effect into account. This is different from introducing procedural guarantees at the level of reception that would potentially mirror equivalent internal decision-making procedures. As pointed out above, these would hardly function as filters for depletion. The procedural adjustment of the type proposed here would apply to the external action of domestic actors, eventually piercing inter- and

[126] See Black, *Constructing and contesting legitimacy...* (n. 11 above), pp. 144-146.

transnational decision-making procedures.[127] Justification, as envisaged here, is important because reason giving creates the conditions for contestation and control, but it can also avoid treating the holders of legally protected interests merely as objects of decision-making.[128] Ultimately, the emphasis on procedural duties of EU institutions and bodies acting in an external role would structure their administrative discretion and avoid "exit ways" that could lead to instances of unrestrained authority.[129]

This way of conceiving the external conduct of domestic administrative actors would be consequential *externally*. If applicable to domestic administrative actors of other jurisdictions gathered in inter- and transnational regulatory fora, the effect would be multiplied. It would then lead to a web of justification that enables legal and political control over the external role of those actors, in the light of the internal laws that bind them. Whether that would be capable of impacting on the procedures followed within those fora in a meaningful way is another matter.[130] Meaningful, from the normative perspective of this paper, would mean finding an adequate way of structuring discretion and constraining authority in internationalised procedures, which would capture the vertical effects of inter- and transnational decisions. Addressing this point would need a deeper understanding of the functioning of these fora, of what it means for the participating members to act under the law, of how incompatible claims inherent to the laws of the participating members could be articulated and which consequences such articulation would entail.[131] However, it is plausible that, if internally constrained by duties of justification that link their external actions back to the substantive and procedural rules that bind them internally, these actors may be pressured also to adjust inter- and transnational decision-making procedures to comply with the same claims of legitimacy they face internally.[132] Internal procedural constrains regarding external

[127] See, for example, the proposal regarding Article 218(9) TFEU, and respective challenges, in Mendes, *EU law and global regulatory regimes* (n. 1, above), pp. 1017-19.
[128] As underlined by Mashaw, "authority without reason is literally dehumanizing"; but justification also proceduralises rationality, thereby converting "the demand for nonarbitrariness into a demand for understandable reason giving" – Mashaw, "Reasoned Administration..." (n. 99, above), p. 118. See also, *idem*, pp. 111, 114 and 115.
[129] On the consequences of such "exit ways", see Benvenisti (n. 7, above).
[130] On the problem of "many hands" of polycentric regulatory regimes, from the perspective of accountability, see Black (n. 11 above), p. 143.
[131] From a different perspective, see, Black (n. 11 above), pp. 143-144, 152-157.
[132] Defending that decision-making in international institutions should reflect the interplay between participating actors, Eyal Benvenisti, *The interplay between actors as a determinant of the evolution of*

regulatory actions of domestic actors could therefore contribute to transform inter- and transnational procedures, given the functional links of the respective decisions. While it would be impossible to accommodate all legitimacy claims stemming from the internal laws of the participating members, it is arguably unlikely that such claims would not have any impact upward in the regulatory chain.[133] Admittedly, the pull towards different procedural rules will most probably come from the most powerful actors in the inter- and transnational scene, eventually spurring criticisms of Americanization or Europeanization of procedures.[134] But this observation only timidly lifts the veil of the more complex factors and incentives that influence decision-making and the relations between actors within the varied inter- and transnational regulatory fora.[135]

5. Conclusions

Regulatory decisions ensuing from decision-making procedures developed at different governance levels may be interlinked in such a way that it may be artificial to ascribe them to distinct legal systems. The argument is not new.[136] Yet, hitherto, the discussion on the internationalisation of EU and national administrative procedures, having highlighted the external ramifications of internal regulatory decisions, has to a large extent ignored the impact that such internationalisation has on procedural guarantees that structure administrative discretion and, hence, constrain public authority exercised through general regulatory acts of varied legal nature and form.[137] Taking as a starting point the author's previous research on this matter, this paper has queried whether internationalised rulemaking procedures may constitute instances of unrestrained

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administrative law in international institutions, 68 LAW AND CONTEMPORARY PROBLEMS 319 (2012). Arguing that, in the case of the ICH, a bottom up insistence on good administrative practices would be the most efficient way to bind network, despite the limitations such approach would have from an accountability perspective, see Berman (n. 27, above), in particular pp. 15, 25-30.

[133] On the possible results of incompatible legitimacy claims, see Black (n. 11 above), pp. 153-157.

[134] In the cases exemplified in the beginning of the paper, the EU is one of the "big four" members of ICCAT, together with the United States, Japan and Canada (Report of the Independent Review, n. 22 above, at 70). With the exception of Canada, these are the same members represented within the ICH. On the impact of ICH guidelines (co-authored by representatives of the EU, US and Japan) vis-à-vis external parties, and the problems this poses, see Berman, (n. 27, above), above.

[135] Benvenisti, (n. 23 above), pp. 325-30.

[136] See n. 113, above.

[137] The case of UN Security Council listing of terrorist and terrorist-associated suspects has of course conspicuously alerted to this problem, but only with regard to decisions with a clear bearing on individual legal spheres. The works of Stewart and of David Lishviz (n. 1, above) constitute exceptions to the observation above, with a focus on the case of the US.

authority and whether they may, as such, defy the premise according to which law ought to ground and limit public authority, upsetting the difficult balance between discretion and law, eventually tipping it to discretion.

Focusing only on the way decisions *are formed* as a result of a combination of a series of acts adopted in inter-, trans- and supranational fora – therefore isolating this aspect from posterior controls that may eventually apply – this paper has argued that unrestrained authority, when it occurs, results from two combined factors: the absence of constraints in the law-making of international bureaucracies that takes into account the vertical effect their acts eventually have by effect of reception; the side-stepping of procedural constraints that would constrain domestic administrative decision-makers if their decisions were adopted only internally and not triggered by reception of external decisions of which they are also authors. By effect of reception, inter- and transnational decisions of varied legal nature – recommendations to which States are legally bound to give effect, guidelines, standards, etc. – eventually become binding on natural and legal persons. Neither the inter- and transnational procedures, nor the EU internal procedures that incorporate them, are designed in a way that considers this effective constraining character of a cascade of interlinked decisions. The problem is enhanced by the arguable limits of judicial review in this respect.

The procedural standards of participation that are depleted by effect of reception have the capacity to structure and constrain the exercise of authority internally. This capacity is absent in the cases of inter- and transnational decision-making analysed. Some of the standards depleted by effect of reception of external decisions do pertain more to administrative practice than to law. Yet, they are capable of fulfilling the function equivalent legal rules of procedure would serve in structuring and defining limits to the exercise of discretion. Notwithstanding the differences between administrative practices and legal rules, procedural standards of participation, irrespective of their origin, nature and rationale, can usefully be re-interpreted with a legal lens and redesigned accordingly. From a legal perspective, they ought to ensure the procedural protection of the legally protected interests affected by decision-making. They do so to the extent that, when accompanied by requirements of justification, they force the decision-makers to duly balance the public and private legally protected interests that they are bound to pursue and respect, by force of the applicable laws. In

this way, procedural constraints of participation and justification can create the conditions to avoid biased decisions that potentially deny material justice.

There are varied meanings of participation, but if re-interpreted and re-designed in the way proposed, procedural standards of participation can be read in the light of the rule of law. There are also varied views on the rule of law, and the possibility that, even with this meaning, participation can be seen as a rule of law requirement is contestable. This paper has endorsed a procedural conception of the rule of law, based on the work of Waldron, and moved on to argue that unrestrained authority challenges the rule of law when there are little or no guarantees of due consideration of the legally protected interests affected by decisions that result from internationalised rulemaking procedures. Lack of procedural guarantees puts at stake the dignity of the persons affected – holders of those interests are treated as objects of decisions in which they do not have a voice. It also hinders the material justice of the public acts adopted – legally protected interests are disregarded while, by law, decision-makers ought at least consider them (as well as the possible effects of their decisions) in the composition of interest that underlies decision-making. In the absence of procedural constrains that ensure due consideration for the legally protected interests affected, the conditions for biased decisions increase, as do the conditions to evade public interests that decision-makers are legally bound to pursue. This is the reason why, in the perspective defended in this paper, the rule of law is challenged when procedural standards of participation are depleted that have the ability to structure discretion and constrain authority in a way that protects those values.

The construction proposed in this paper would require, first, a re-interpretation of the procedural standards of participation that are currently in place not only in inter- and transnational procedures but also in the EU. In the EU, current procedural constraints triggered by concerns of transparency, responsiveness and accountability have the capacity of functioning as legal guarantees against unrestrained authority, or at least can be re-interpreted in this light. In the decision-making procedures analysed, this capacity is absent at the international and transnational levels. While the EU institutional practices are closer to the transformation proposed here, approaching them from a rule of law perspective would require that they would be capable of functioning as effective constraints. This stresses the limits of current EU procedures and procedural

practices. They would need to be transformed accordingly. The effect would be creating legality (or quasi-legality) where it has not existed hitherto. The advantages and disadvantages of this transformation would need to be balanced in each regulatory setting.

Importantly, this transformation would only be capable of constraining the exercise of authority that results from internationalised procedures if accompanied by a new way of approaching these procedures. Instances of exercise of authority can only be adequately identified if the procedures that operate the coordination of the different legal systems involved stop being viewed in segmented terms from a multi-level perspective. Likewise, adequate solutions to structuring discretion and constraining authority depend on viewing internationalised procedures in their entirety, focusing on the functional interdependence of the segments developed at different levels of governance, and thereby capturing the regulatory chain triggered by decisions adopted at the inter- or transnational level. Ultimately, this perspective may lead to a re-conceptualisation of the administrative procedures that operate the coordination of decisions taken in different regulatory sites. The paper discussed the potential explanatory value but also the difficulties of constructing them as composite procedures. Alternatively, it suggested an actor-based approach to re-design internationalised procedures, in the light of the domestic ramifications of their external decisions, by focusing on the procedural duties of domestic actors when acting in an external role.

Framing the problem of depletion of procedural standards from the normative perspective proposed in this paper highlights that, in whichever way processes of regulating public interests are organised, decisions made in pursuance of public interests should be linked back to the law that identifies them, with all this linkage symbolically entails. Decision-making processes where the balancing of competing public interests takes place are undoubtedly political and technical processes. In this sense, law may have a very limited role in defining the boundaries of the positive action of decision-makers. Be that as it may, there ought to be mechanisms that ensure decision-makers balance and duly consider the effects their decisions have in legally protected interests, while still acting within their mandate legal. Participation and justification, as approached in this paper, is one of such mechanisms and can, as such,

constitute a guarantee that internationalised administrative procedures are not bypassing and denying the law.