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European Agencies' Rulemaking: Powers, Procedures and Assessment

*Edoardo Chiti**

Abstract: *This article aims at identifying European agencies' rulemaking powers, mapping the procedures through which such powers are exercised and assessing the existing procedural arrangements. The first section analyses the main forms of European agencies' rulemaking. It shows, on the one hand, that not all European agencies are actually engaged in the adoption of administrative rules, on the other hand, that European agencies carrying out rulemaking activities tend to converge on two specific forms of rulemaking, namely participation in the adoption of binding implementing rules and regulation by soft law. The second section, devoted to mapping the procedures through which rulemaking powers are exercised, argues that the two main types of European agencies' rulemaking cannot be said to be subject to a really common procedural framework. In both cases, the emerging procedural rules implement the same principles of transparency and participation and rely on the same consultation mechanism, sometimes complemented by regulatory impact assessment. Yet, proceduralisation has an uneven development: while the establishment of a procedural discipline is quite common with reference to participation in the adoption of binding implementing rules, regulation by soft law remains largely under-proceduralised. The last section proposes an assessment of the European agencies' rulemaking procedures. Two main shortcomings are identified: the asymmetry between the tendency to proceduralise the adoption of binding implementing rules and the parallel tendency to keep informal the process of adoption of soft law measures; and the too rudimental development of consultation.*

I Purpose

Do European agencies (EAs) exercise *de jure* or *de facto* non-legislative rulemaking powers? What procedural principles, rules and practices do they follow when carrying out their rulemaking activities? Is a procedural framework made up of principles, rules and practices common to most EAs in the process of emerging? If so, what are its constitutive elements and its degree of formalisation and detail? And how can one assess the existing procedures governing EAs' rulemaking?

In order to collect elements useful to answer such questions, this article aims at mapping EAs' rulemaking powers, identifying the procedures through which such powers are exercised, and discussing the existing procedural arrangements.

* Full Professor, Tuscia University, Viterbo, Italy.

Before beginning the inquiry, one brief clarification is needed. Within the context of this article, the notion of European agency is used to refer to a specific organisational arrangement, distinct from other contiguous models of the EU administration. Building on previous research on the topic,[1] EAs are here meant as bodies (1) aimed at establishing and managing a plurality of cooperative relationships involving both the Commission and the Member States' administrations; and (2) enjoying a certain degree of autonomy from the Commission but not fully insulated from the Commission's influence. We will try to clarify in section II what bodies may actually be considered as belonging to such overall conception of the agencification phenomenon in the EU. What is important to point out since the beginning, however, is that in this article a number of bodies often considered as belonging to the EAs' family will be excluded from consideration. This is the case, in particular, of the EU administrative bodies presenting a marked transnational character—such as Europol, Eurojust and the European Police College (Cepol)[2]—and of the EU independent authorities, exemplified by the European Central Bank (ECB). The inquiry will include, instead, the new bodies established in the field of energy and financial supervision, here considered more as a complication of the model of EAs than as genuinely independent authorities in the sense exemplified by the ECB architecture.[3]

The structure of the article is simple enough. The article opens with a discussion of the main forms of EAs' rulemaking (section II). The following section will be devoted to mapping the procedures through which the rulemaking powers identified in the previous section are exercised (section III). The current procedural architecture will then be assessed in the last section (section IV). A short concluding section will summarise the line of thoughts presented in the article (section V).

II European Agencies' Rulemaking

A Regulatory Agencies without Regulatory Powers?

EAs are rarely, if ever, associated with rulemaking. Those authors who recognise in the agencification process the emergence of a traditional type of public administration have mostly focused on the instrumental or adjudicatory powers of the new EAs. And even scholars inclined to recognise an embryonic form of independent regulatory authorities in the EAs have come to the conclusion that they cannot adopt general regulatory measures, acknowledging that 'the only formula that seems to be acceptable to the Brussels authorities is an oxymoron: a regulatory agency without regulatory powers.'[4]

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[1] E. Chiti, 'An Important Part of the EU's Institutional Machinery: Features, Problems and Perspectives of European Agencies', (2009) 46 *Common Market Law Review* 1395; E. Chiti, 'Existe-t-il un modèle d'Agence de l'Union européenne?', in J. Molinier (ed.), *Les agences de l'Union européenne* (Bruylant, 2011), at 49.

[2] These bodies are considered as EAs in several reconstructions: see, eg P. Craig, *European Union Administrative Law* (Oxford University Press, 2nd edn, 2012), at 144; M. Busuioc, *The Accountability of European Agencies. Legal Provisions and Ongoing Practices* (Eburon, 2010) 35; M. Groenleer, *The Autonomy of European Agencies. A Comparative Study of Institutional Development* (Eburon, 2009); D. Curtin, *Executive Power of the European Union. Law, Practices, and the Living Constitution* (Oxford University Press, 2009), at 146.

[3] For this interpretation, see E. Chiti, 'Le trasformazioni delle agenzie europee', (2010) 59 *Rivista trimestrale di diritto pubblico* 57.

[4] G. Majone, *Dilemmas of European Integration. The Ambiguities and Pitfalls of Integration by Stealth* (Oxford University Press, 2005), at 93.

Yet, EAs exercise *de jure* or *de facto* rulemaking powers. Admittedly, such powers are of limited relevance, which reflects both the political reluctance of EU institutions to grant EAs genuine rulemaking powers and a certain shyness of EAs themselves to fight to acquire rulemaking powers on the ground. Nevertheless, these powers are used by EAs as one of the various instruments through which the implementation of EU legislation is carried out and the objective of the smooth functioning of the relevant policy sectors is pursued.

In order to identify the main forms that rulemaking may take, it is convenient to consider how the different groups of EAs are involved in the exercise of rulemaking powers. Three main 'functional families' of EAs will be considered in this regard: (1) EAs provided with genuinely final, decision-making powers; (2) EAs coordinating common systems providing an advisory or technical assistance to European and national institutions; (3) EAs coordinating common systems responsible for the production of high-quality information in certain specific sectors of EU action. For each group, we will consider the possible involvement in rulemaking and the specific ways in which this may take place.

B Agencies Provided with Decision-Making Powers

The group of EAs provided with genuinely final, decision-making powers includes several old and new EAs. Among the first generation of EAs, one may refer to the Office for Harmonization in the Internal Market (OHIM), which carries out the procedures for the Community trademarks and registered designs, and to the Community Plant Variety Office (CPVO), deciding on applications for Community plant variety rights and managing the relative administrative procedures.[5] A third body provided with final powers is the European Chemicals Agency (ECHA), which ascertains the completeness of registrations submitted by manufacturers and importers and rejects them when they lack one or more required elements, although it should be noticed that it participates with merely consultative powers in the procedures concerning trade authorisations, while the final administrative decision is left to the Commission.[6] More recently, this family of EAs has been enriched by the new European supervisory authorities (so called ESAs, which include a European Banking Authority, a European Insurance and Occupational Pensions Authority and a European Securities and Markets Authority), established as a response to the financial crisis and coordinating national supervisors within a 'European System of Financial Supervision.'[7]

Most of these agencies are engaged in some sort of regulation by soft law. For example, the president of the OHIM may issue notices and information of a general character, relevant to the establishing regulation or its implementation, which are then published in the Official Journal of the Office itself as well as on its web site.[8] Analogously, the president of the CPVO may issue 'notices' to ensure the functioning

[5] The powers of the Office for Harmonisation in the Internal Market (Trade Marks and Designs) (OHIM) are regulated by Reg 207/2009, O.J. 2009, L 78, codifying Reg 40/94 and subsequent amendments; as for the Community Plant Variety Office, see Reg 2100/94, O.J. 1994, L 227, as subsequently amended.

[6] Reg 1907/2006, O.J. 2006, L 396.

[7] See Reg 1093/2010, Reg 1094/2010 and Reg 1095/2010, all in OJ 2010 L 331.

[8] Art 89, Reg 207/2009, cit.

of the office.[9] The ECHA provides technical and scientific guidance for the application and operation of the establishing Regulation.[10] And the ESAs may issue guidelines and recommendations to national authorities and financial institutions with a view to establishing consistent and effective supervisory practices and to ensuring the uniform application of EU law. These guidelines and recommendations are not legally binding. Yet, the competent authorities and financial institutions 'shall make every effort to comply with those guidelines and recommendations' and are called to provide reasons for non-compliance.[11]

Only some of these agencies, instead, are provided the power to participate in procedures leading to the adoption of binding implementing rules. For example, the ECHA sends its recommendation to the Commission within the context of the committee procedure of inclusion of substances in the Annex to the establishing Regulation listing the substances subject to authorisation.[12] The most accomplished case, though, is that of the ESAs. First, the ESAs have the task to develop draft regulatory technical standards, implying neither strategic decisions nor policy choices, in the areas within the scope of the powers delegated to the Commission under EU financial services law and in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU). In particular, the ESAs submit their drafts to the Commission, which may then endorse them as delegated acts, reject them or endorse them in part or with amendments after coordinating with the relevant ESA. Second, the ESAs may develop draft implementing technical standards in the areas where financial services law provides the Commission with powers for issuing uniform conditions for the implementation of EU law in accordance with Article 291 TFEU. The procedure envisaged by the establishing Regulations is analogous to that governing the adoption of regulatory technical standards.

C Agencies Provided with Instrumental Powers

A second group is that of EAs that are not provided with genuinely final, decision-making administrative powers but are rather called to coordinate transnational administrative networks providing an advisory or technical assistance to European and national institutions.[13]

EAs belonging to this functional family are mainly engaged in administrative rulemaking by participating in the procedures leading to the adoption of binding implementing rules, either by assisting the Commission or by directly adopting technical rules.

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[9] Art 42, Reg 2100/94, cit.

[10] Art 77/2, Reg 1907/2006, cit.

[11] See, eg Art 16 Reg 1093/2010, cit.

[12] Art 58, Reg 1907/2006, cit.

[13] The agencies carrying out an advisory or technical assistance function *vis-a'-vis* European and national institutions are the following: the European Medicines Agency (1993), the Translation Centre for the Bodies of the European Union (1994), the European Agency for Reconstruction (1999), the European Food Safety Authority (2002), the European Maritime Safety Agency (2002), the European Aviation Safety Agency (2002), the European Network and Information Security Agency (2004), the European Centre for Disease Prevention and Control (2004), the European Railway Agency (2004), the European Agency for the Management of Operational Cooperation at the External Borders—Frontex (2004), the European GNSS Supervisory Authority (2004), and the Community Fisheries Control Agency (2005), the Agency for the Cooperation of Energy Regulators (2009).

Examples of assistance to the Commission in technical rulemaking procedures are provided by the European Network and Information Security Agency (ENISA), by the European Maritime Safety Agency (EMSA) and by the Agency for the Cooperation of Energy Regulators (ACER). The first is responsible for assisting the Commission, where called upon, in the technical preparatory work for updating and developing EU legislation in the field of network and information security.[14] Analogously, the EMSA is called to assist the Commission, where appropriate, in the preparatory work for updating and developing EU legislation in the fields of maritime safety and maritime security, the prevention of pollution and response to pollution caused by ships, in particular in line with the development of international legislation in that field.[15] And the ACER assists the Commission in several regulatory tasks, as when it submits the network code to the Commission and recommends that it be adopted.[16]

A further example is that of the European Railway Agency (ERA), which is called to contribute, on a technical level, to the establishment of a 'European railway area without frontiers and guaranteeing a high level of safety' through the adoption of recommendations and opinions to the Commission. As for rulemaking, in particular, the Agency (1) is required to draw up the draft of a reference document classifying all the technical and safety rules in force in each Member State for placing vehicles in service; (2) may be called upon by the Commission to provide technical opinions on urgent modifications to technical specifications for interoperability; (3) and issues some recommendations to the Commission, as happens when it recommends to the Commission common specifications for the various existing registers.[17]

Among the EAs entrusted with the power not only to assist the Commission in the exercise of rulemaking powers but also to directly adopt technical rules, one may refer to the European Aviation Safety Agency (EASA). On the one hand, the EASA assists the Commission by preparing measures to be taken for the implementation of the establishing Regulation. In doing this, the role of the EASA is that of a specialised advisor that has to be consulted: where the implementing measures comprise technical rules, the Commission may not change their content 'without prior coordination with the Agency.'[18] On the other hand, the EASA has the power to issue technical rules, referred to by the establishing Regulation in the terms of 'certification specifications and acceptable means of compliance.'[19] The relevance of such direct rulemaking powers is reflected at the organisational level by the establishment of a 'rulemaking directorate' within the EASA.

Though mainly called to contribute to the adoption of binding implementing rules, EAs providing an advisory or technical assistance to European and national institutions may also be engaged in rulemaking by soft law.

A remarkable example is that of the European Medicines Agency (EMA). The EMA is not expressly entrusted with rulemaking powers by the establishing

[14] Art 2/4, Reg 460/2004, O.J. 2004 L 77.

[15] Reg 1406/2002, O.J. 2002 L 208/1, as subsequently amended; Art 2 a) of the consolidated version available at the web site http://www.emsa.europa.eu/about/legal-basis.html

[16] Art 6, Reg 713/2009, O.J. 2009 L 211.

[17] See Reg 881/2004, O.J. 2004, L 164/1, as amended by Reg 1335/2004, OJ 2008 L 354/51.

[18] See Reg 216/2008, as subsequently amended; Art 17/2 b) of the consolidated version available at the web site http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R0216:20091214:EN:PDF

[19] *ibid.* Art 18 c). Technical rules are complemented by soft law measures, broadly indicated as 'any guidance material for the application of this Regulation and its implementing rules.'

Regulation. And it seems rather reluctant to interpret its mission in such a way as to engage in the exercise of rulemaking tasks. Yet, it issues technical, scientific and procedural guidance concerning the implementation of the EU pharmaceutical legislative framework. Depending on their contents, guidelines are then published either in the volumes of the Rules governing medicinal products in the EU or on the web site of the EMA. Guidelines' overall function is to provide 'advice to applicants or marketing authorisation holders, competent authorities and/or other interested parties on the best or most appropriate way to fulfil an obligation laid down in the community pharmaceutical legislation.'[20] Their legal status is that of soft law measures, inherently in tension between the form of non-binding provisions and the substance of rules *de facto* affecting and conditioning private parties' behaviours. Such ambiguity is well reflected by the somehow clumsy explanation given by the Agency itself, according to which guidelines 'are "soft law" non-legally binding but quasi-binding character that can derive from the legal basis when the guideline intends to specify how to fulfil a legal obligation (example Article 106 of Directive 2001/83/EC concerning pharmacovigilance). However, guidelines are to be considered as a harmonised Community position, which if they are followed by relevant parties such as the applicants, marketing authorisation holders, sponsors, manufacturers and regulators will facilitate assessment, approval and control of medicinal products in the EU. Nevertheless, alternative approaches may be taken, provided that these are appropriately justified.'[21]

D Information Agencies

The third and final group is that of EAs coordinating common systems responsible for the production and dissemination of high-quality information in certain specific sectors, such as environmental information, vocational training, life and work conditions, drugs and drug addiction, destined to be used by European and national institutions in the exercise of their decision-making powers. It is a significant family of EAs, not only because it represents the predominant group of EAs,[22] but also because, even if their powers may be less notable than those granted to other European administrations, the importance of the production and dissemination of high-quality information should not be underestimated, as it plays a decisive role in the implementation of European policies.

Interestingly enough, 'information agencies' are not formally granted rulemaking powers. Nor is there any evidence of the fact that they exercise *de facto* rulemaking powers, for example to promote through soft law administrative integration within the sectoral network they coordinate. Even the cases in which the information function is used as a regulatory technique should not be considered as genuine examples

[20] See EMA, *Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework*, 18 March 2009, Doc. Ref. EMEA/P/24143/2004 Rev. 1 corr., 4.

[21] *ibid.* 4–5.

[22] The EAs carrying out a function of production and dissemination of information are the following: the European Centre for the Development of Vocational Training—Cedefop (1975), the European Foundation for the Improvement of Living and Working Conditions—EUROFOUND (1975), the European Environment Agency (1990), the European Training Foundation (1990), the European Monitoring Centre for Drugs and Drug Addiction (1993), the European Agency for Safety and Health at Work (1994), the European Union Agency for Fundamental Rights (2007), which substitutes the former European Monitoring Centre on Racism and Xenophobia.

of rulemaking: as it was observed since the very beginning of the experience of information agencies, 'regulation by information' is one of the possible outcomes of EAs' action;[23] yet, regulation by information normally affects specific subjects and is exercised to orientate their conduct and behaviour, such as in the case of a document listing unsafe aviation companies which should induce the companies to meet higher safety requirements.

The only information agency involved in rulemaking is the EU Agency for Fundamental Rights (FRA). According to its establishing Regulation, the FRA 'shall formulate and publish conclusions and opinions on specific thematic topics, for the Union institutions and the Member States when implementing Community law, either on its own initiative or at the request of the European Parliament, the Council or the Commission.'[24] In this case, the FRA participates, by virtue of its knowledge and expertise, in procedures leading to the adoption of binding implementing rules. Involvement in rulemaking may extend beyond the areas determined by the FRA's Multiannual Framework, but only if its financial and human resources so permit.[25] Moreover, the FRA's conclusions and opinions cannot deal with the legality of EU acts or with the question of whether a Member State has failed to fulfil an obligation under the Treaty.[26]

E Between Binding Implementing Rules and Soft Law

The inquiry developed so far suggests two conclusions.

To begin with, not all the groups of EAs are actually engaged in rulemaking. While rulemaking activities are carried out by EAs provided with genuinely decision-making powers and by some EAs providing an advisory or technical assistance to European and national institutions, information agencies seem extraneous to any type of rulemaking.

Moreover, when carrying out rulemaking activities, EAs tend to converge on certain specific forms of rulemaking. More precisely, if we leave aside the participation of certain EAs in legislative rulemaking, ie to the procedures leading to the adoption of EU legislation by sector, two main types of agencies' rulemaking can be identified. First, EAs may be called to participate, as technical actors, in procedures leading to the adoption of binding implementing rules, either assisting the Commission or directly adopting technical rules. Second, EAs are often formally or *de facto* granted the power to issue guidance, application guides, communications and other soft law instruments, either to the regulatees or to other administrations participating in the sectoral network they coordinate. Participation in the adoption of binding implementing rules and regulation by soft law are differently developed in the two families of EAs involved in rulemaking—namely EAs provided with decision-making powers and EAs providing an advisory or technical assistance to European and national institutions. Taken together, though, they represent the main contribution of EAs to administrative rulemaking: it is through participation in the adoption of

[23] See in particular G. Majone, 'The New European Agencies: Regulation by Information', (1997) 4 *Journal of European Public Policy* 262.

[24] Art 4/2 Reg 168/2007.

[25] *ibid.* Art 5/3.

[26] *ibid.* Art 4/2.

binding implementing rules and regulation by soft law that EAs seem to provide a substantial regulatory contribution to the smooth functioning of their policy sectors.

The engagement of EAs in rulemaking activities obviously raises several issues, ranging from the legal, political and functional reasons that explain the specific forms taken by EAs' rulemaking to the interaction between rulemaking and the other powers that EAs are granted in order to ensure the effective implementation of certain pieces of EU legislation by sector. Such issues, however, fall outside the scope of this inquiry, which primarily focuses on the procedural dimension of rulemaking. It is to procedural rules and practices governing EAs' rulemaking that we need to turn our attention. This will be done in the next section.

III The Procedural Framework

If some EAs are involved in rulemaking, what procedural rules and practices do they follow in the exercise of their rulemaking powers? EAs are certainly subject, as any other EU body, to the principles of administrative proceedings resulting from the case-law of the European Court of Justice (ECJ) and the General Court, the Treaties and the Charter of Fundamental Rights of the EU.[27] Yet, which principles are relevant for EAs' rulemaking? And how are they implemented and translated in specific rules and administrative practices? Can a procedural framework made up of principles, rules and practices common to most of the EAs' rulemaking activities be envisaged in the process of emerging? If so, does it reflect the differences between the two main types of EAs' rulemaking, ie participation in procedures leading to the adoption of binding implementing rules and regulation by soft law? Or are these two main types of rulemaking subject to the same procedural principles and rules? And what is the degree of formalisation and detail of the emerging procedural framework?

A Participation in Procedures Leading to the Adoption of Binding Implementing Rules

In the attempt to give an answer to this set of issues, one should first consider the EAs' participation in those procedures leading to the adoption of binding implementing rules.

Three main elements may be highlighted in this regard. First, the overall procedural context of agencies' participation significantly varies from case to case. For example, as it has been previously recalled, the ESAs may submit to the Commission draft regulatory technical standards within the context of a delegation of powers by the European Parliament and the Council to the Commission under Article 290 TFEU. But they may also issue draft implementing technical standards in the areas where financial services law provides the Commission with powers for establishing uniform conditions for the implementation of EU law in accordance with Article 291 TFEU. Moreover, EAs established before the entry into force of the TFEU may participate in different types of procedures escaping the new framework provided by the Lisbon

[27] For a detailed account of these principles, see P. Craig, *European Union Administrative Law*, *op cit* 320; H.C.H. Hofmann, G.C. Rowe and A.H. Türk, *Administrative Law and Policy of the European Union* (Oxford University Press, 2011), at 190; J. Mendes, *Participation in EU Rule-Making. A Rights-Based Approach* (Oxford University Press, 2011); J.-B. Auby and J. Dutheil de la Rochère (eds), *Droit Administratif Européen* (Bruylant, 2007), at 321.

Treaty. Such procedures may be committee procedures, ending up with a Commission rulemaking measure but also procedures that do not involve the Commission, as happens when the EASA issues technical rules.

Second, within this highly variable overall procedural context, EAs seem to go through a process of gradual convergence as for the procedures followed to issue the measures through which they contribute to administrative rulemaking. Indeed, in most cases the consolidation of rulemaking powers is accompanied by a process of proceduralisation, reflecting some fundamental principles of administrative action and centred upon a number of recurrent mechanisms. Admittedly, a great deal of technical solutions may be registered and variations among the procedural practices of the different EAs are unsurprisingly abundant. Yet, what is important not to miss is the overall tendency of most EAs to converge on a specific procedural pattern, as well as the capacity of certain EAs to act as a model and as a source of inspiration for the other agencies.

The regulatory frameworks of the ACER and the ESAs provide two prominent examples of proceduralisation. These two cases are strikingly similar. In both cases, the main legal source is the establishing Regulation. The elaboration of the various measures through which the agency participates in the rulemaking procedures is made subject to the same procedural principles, namely those of participation and transparency. And such principles are implemented by procedural rules that are structurally similar, namely consultation, both of national administrations and of private parties, and publication of the measure. Indeed, the ACER, in carrying out its tasks, and in particular in the process of developing framework guidelines and proposing amendments of network codes, is due to 'consult extensively and at an early stage with market participants, transmission system operators, consumers, end-users and where relevant, competition authorities, without prejudice to their respective competence, in an open and transparent manner, in particular when its tasks concern transmission system operators.'[28] As for the ESAs, the development of draft regulatory technical standards in the areas within the scope of the powers delegated to the Commission is carried out through a procedure based upon 'open public consultations on draft regulatory technical standards' and request of advice from the relevant stakeholder group, complemented by an analysis of 'the potential related costs and benefits.'[29] These are necessary procedural steps, unless consultations and analyses are considered disproportionate in relation to the scope and impact of the draft regulatory technical standards concerned or in relation to the particular urgency of the matter. And the same procedure applies to the development of draft implementing technical standards.[30]

Third, the overall tendency is to formalise only a very basic procedural outline. The procedural discipline is often just a skeleton of basic provisions, which would deserve further elaboration and development. In particular, the establishing regulations and the EAs' internal rules of procedure often reaffirm the relevance of the principles of participation and transparency and envisage mechanisms of consultation. But they very rarely go into the details of the different phases of rulemaking, such as agenda setting, the definition of precise modalities of involvement of the various relevant

[28] Art 10/1, Reg 713/2009, O.J. 2009 L 211, Art 10/1.
[29] See, eg Art 10/1, Reg 1093/2010, cit.
[30] See, eg Art 15/1, Reg 1093/2010, cit.

actors through consultation, the identification of a subject ultimately responsible for rulemaking, and the publication requirements.

Examples of a rather low degree of formalisation are provided by the ENISA, the EMSA and the ERA. The ENISA and the EMSA are subject to a duty of transparency in the carrying out of their activities. Yet, neither the establishing regulations nor their rules of procedure provide any procedural rule specifically designed to the agency's activity of assistance to the Commission in the technical preparatory work for updating and developing EU legislation by sector. As for the ERA, even if it is not subject to a general duty of public consultation, its establishing Regulation provides that it shall consult 'the social partners within the framework of the sectoral dialogue committee' and the organisations representing rail freight customers and passengers whenever its work has a direct impact, respectively, on the social environment or working conditions of workers in the industry and on users.[31] In both cases, consultations have to be held before the ERA submits its recommendations to the Commission and have to be taken in the due account.

A remarkable exception is represented by the EASA. The founding regulation establishes certain basic rules to be followed in all the procedures aimed at the development of opinions, certification specifications and guidance material. Such rules respond to the exigencies of transparency and participation of the various interested actors—experts, national agencies, affected persons and the public at large. They are then specified and complemented by a Decision of an EASA Management Board Decision concerning the rulemaking procedure.[32] The decision is a fundamental source because it implements the principles of participation and transparency through a number of detailed provisions regulating all the various steps of the procedure, such as agenda setting and regulatory impact assessment, the precise modalities of consultation, the identification of a subject responsible for the rulemaking procedure and the publication requirements.

B Regulation by Soft Law

The second main type of agencies' administrative rulemaking, ie regulation by soft law, is subject to tendencies that are partly different and partly similar to those related to the adoption of binding implementing acts.

The main difference lies in the extremely low degree of proceduralisation. There is no evidence of an overall tendency to formalise the procedures through which soft law measures are adopted. In most cases, neither the establishing regulations nor the EAs' rules of procedure envisage any kind of procedural provision concerning the elaboration and adoption of soft law measures. And the information available on the EAs' web sites does not suggest the existence of consolidated administrative practices. Only few agencies proceed in the direction of a proceduralisation of soft law rulemaking. This is the case, in particular, of the EMA and of the new ESAs. As for the EMA, the procedure concerning the adoption of soft law measures is regulated by another soft law measure, namely the already mentioned guidelines devoted to a *Procedure for European Union Guidelines and Related Documents within the Pharmaceutical*

[31] See Art 4 and Art 5, Reg 881/2004, cit.

[32] See EASA Management Board Decision 08-2007, amending and replacing Decision 07/2003 concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications and guidance material ('rulemaking procedure').

Legislative Framework. As for the ESAs, the procedure for the adoption of guidelines and recommendations is provided by establishing regulations themselves.

When some sort of proceduralisation of soft law rulemaking takes place, however, it tends to replicate the structure and rationale of the emerging procedural framework for the adoption of binding implementing acts. Indeed, the European legislator and EAs themselves show a clear intention not to differentiate between these two distinct levels of administrative rulemaking. As in the case of the adoption of binding implementing acts, the procedural provisions are explicitly based upon the principles of transparency and participation, and they are aimed at implementing these principles essentially through consultation and publication of the measure, sometimes complemented by regulatory impact assessment.

For example, when issuing guidelines and recommendations addressed to competent authorities or financial institutions, the ESAs have to follow a procedure similar to those envisaged in relation to the adoption of draft regulatory technical standards and draft implementing technical standards. As in those cases, the ESAs are called to conduct open public consultations regarding the proposed guidelines and recommendations and to analyse the related potential costs and benefits. Consultations and analyses have to be proportionate to the scope, nature and impact of the guidelines or recommendations. And the ESA has to request opinions or advice from the relevant stakeholder group. The only, but substantial, difference lies in the circumstance that both the launch of consultation and the request of opinions or advice from the relevant stakeholder group are left to the choice of the ESAs, which may conduct them 'where appropriate.'[33]

A further analogy with the adoption of binding implementing acts is that proceduralisation is limited to the establishment of a number of very basic provisions, and the relevant rules do not go into the details of the various phases of rulemaking. The EMA, though, provides a remarkable counter-example. Its guidelines laying down the procedure for the adoption of soft law measures regulate with a great deal of detail the various steps of the procedure. Such steps include the 'selection of topic and inclusion in the relevant work programme,' the appointment of a rapporteur, the development of a 'concept paper,' the adoption and release for consultation of concept paper, the preparation of initial draft guideline, the release for consultation of draft guideline, the collection and treatment of comments, the preparation and adoption of final guideline, the implementation and revision of adopted guidelines.[34]

C Common Orientations, Uneven Developments

The analysis carried out in this section suggests some general observations.

As for their participation in the adoption of binding implementing rules, EAs appear to converge on a common procedural pattern. In most cases, the procedure followed to issue the measure through which EAs contribute to administrative rulemaking is made subject to two fundamental principles of administrative action, namely the principles of transparency and participation, and is centred upon consultation, sometimes complemented by regulatory impact assessment. The emerging procedural framework is often just a skeleton of basic provisions, requiring further

[33] See, eg Art 16 of Reg 1093/2010, cit.

[34] See EMA, *Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework*, cit.

elaboration and development. Yet, the detailed procedural rules governing the EASA's rulemaking represent a remarkable exception and might be taken by other EAs as a source of inspiration for rulemaking procedures.

Moreover, as for regulation by soft law, there is no evidence of an overall tendency to formalise the procedures through which soft law measures are adopted. When existing, though, the procedural rules for soft law are explicitly based upon the principles of transparency and participation, and they are aimed at implementing such principles essentially through consultation and publication of the measure, sometimes complemented by regulatory impact assessment. Proceduralisation is, in any case, limited to the very basic provisions and the relevant rules do not go into the details of the various phases of rulemaking, although the EMA provides a significant counter-example, potentially capable of operating as a model for other EAs.

Finally, the two main types of EAs' rulemaking—contribution to the adoption of binding implementing rules and regulation by soft law—cannot be said to be subject to a really common procedural framework. In both cases, the emerging procedural rules implement the same principles of transparency and participation and rely on the same consultation mechanism, sometimes complemented by regulatory impact assessment. Yet, proceduralisation has an uneven development: while the establishment of a procedural discipline is quite common with reference to participation in the adoption of binding implementing rules, regulation by soft law remains largely under-proceduralised.

IV An Assessment: Two Procedural Issues

Admittedly, the high fragmentation and limited consolidation of the procedural rules for EAs' rulemaking do not allow a clear-cut assessment of the current regime. In the broad perspective taken in this article, however, two intertwined questions may be raised. First, whether the asymmetry between the tendency to proceduralise the process of adoption of binding implementing rules and the parallel tendency to keep informal the process of adoption of soft law measures is justifiable or should be instead considered as a shortcoming of the current regime. Second, whether the emerging principles and rules are appropriate to govern the main forms of EAs' rulemaking or deserve and need certain corrections.

A The Asymmetry between Proceduralisation and Informality

As for the first issue, one should begin by observing that a number of general reasons, both functional and normative, support the choice in favour of proceduralisation within the European administrative system. Administrative proceedings operate both as instruments of administrative integration in the multi-level European administrative system[35] and as institutional mechanisms to structure the relationships between

[35] As a technique of administrative integration, administrative proceedings aim at making possible a coherent action of the multiple (national, EU and mixed) administrative bodies responsible for carrying out a specific public function; for this perspective, see in particular E. Chiti and C. Franchini, *L'integrazione amministrativa europea* (Il Mulino, 2003); H.C.H. Hofmann and A.H. Türk (eds), *EU Administrative Governance* (Edward Elgar, 2006); E. Chiti, 'The Administrative Implementation of European Union Law: A Taxonomy and Its Implications', in H.C.H. Hofmann and A.H. Türk (eds), *Legal Challenges in EU Administrative Law: Towards an Integrated Administration* (Elgar Publishing,

EU administrations and the addressees of administrative action. Moreover, proceduralisation may be constructed as a tool capable of providing a specific form of legitimacy to the European administrative system,[36] for example as a component of accountability regimes.[37]

There is, though, no single answer to the question of proceduralisation but only solutions contingent and variable from case to case. Proceduralisation is neither justified *per se* nor a one-size-fits-all solution: different functional and normative circumstances may require different answers and degrees of proceduralisation, including the no-proceduralisation option.

EU administrative law itself provides several examples of administrative action that is reasonably not made subject to procedural principles and rules. This is what happens in the administrative networks coordinated by EAs and responsible for the production and dissemination of high-quality information in certain fields of EU action. In these cases, the effect of administrative integration is not pursued through the provision of administrative proceedings but through the provision of non-binding, soft law instruments, such as the work programme adopted by the relevant European agency, aimed at stabilising in a non-coercive way the conducts of the various competent bodies. These non-procedural instruments of administrative integration seem to find their functional foundation in the peculiar nature of the performed activity, which relies on a multiplicity of interpretative processes eluding the cohesive force of the traditional procedural tools.[38] The lack of proceduralisation, moreover, may be justified, at least in part, also with regard to the relationships between the European administrative networks and the addressees of administrative action. As it has been already observed, information production can assume different connotations, including that of regulation by information. In all these cases, however, the relationships between the European agency and the addressees of administrative action are mainly indirect and mediated, and they can be structured and regulated through instruments different from administrative proceedings, such as, for example, organisational arrangements.

When applied to EAs' rulemaking, in any case, the functional approach to proceduralisation leads to a conclusion that is different from that of the previous example. The limited proceduralisation of EAs' rulemaking, and in particular the asymmetry between a rather consolidated set of procedural principles and rules for the adoption of binding implementing measures and the lack of formalised procedures governing the adoption of soft law, might be considered as a simple reflection, at the procedural level, of a qualitative difference between two types of administrative rulemaking,

2009), at 9; on the notion of 'composite proceedings' see, in particular, S. Cassese, 'European Administrative Proceedings', and G. della Cananea, 'The European Union's Mixed Administrative Proceedings', both in F. Bignami and S. Cassese (eds), *The Administrative Law of the European Union* (2004), at 68 *Law and Contemporary Problems* respectively 21 and 197; and H.C.H. Hofmann, 'Composite Decision Making Procedures in EU Administrative Law', in H.C.H. Hofmann and A.H. Türk (eds), *Legal Challenges in EU Administrative Law: Towards an Integrated Administration, op cit* 136.

[36] In this vein, for example, L. Azoulay, 'The Judge and the Community's Administrative Governance', in C. Joerges and R. Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford University Press, 2002), at 109, 132–133.

[37] This perspective is developed by E. Chiti, 'L'accountability delle reti di autorità amministrative dell'Unione europea', (2012) 21 *Rivista italiana di diritto pubblico comunitario* 29.

[38] See E. Chiti, 'An Important Part of the EU's Institutional Machinery', *op cit* 1409; see also Id., 'On European Agencies', in J. Eriksen, C. Joerges and J. Neyer (eds), *European Governance, Deliberation and the Quest for Democratisation* (Arena Report No. 2, 2003), at 275.

namely binding rulemaking and soft law. At the same time, however, one might wonder whether the coexistence of two distinct arrangements, one based upon administrative procedures and the other based upon informality, is really justified in this context. The two types of EAs' rulemaking are oriented to govern homogenous fact and situations and less different in terms of legal strength than it is usually assumed. Maintaining a double decision-making process, one proceduralised and the other informal, might result in a loss of coherence of administrative action within a single European agency or among different EAs. Moreover, both in the case of binding and soft law rulemaking, there is a need to encourage private subjects to take part in the action of the EAs, with a view towards controlling their rulemaking activity, as well as towards providing EAs with relevant information and guaranteeing that recognition and representation of facts and interests in the rulemaking process are complete. This may be done within the context of administrative proceedings, which provide a legal environment suitable to apply the so-called 'interest representation model.' On the one hand, a great deal of attention may be devoted to the emerging of interests that might influence public decisions. On the other, instead of being hierarchically ordered by the legislator, such interests can be compared in the framework of the administrative procedure, 'so as to ensure decisions grounded on the knowledge of facts and on a reasonable and justified balance of the interests.'[39]

These observations suggest that the lack of formalised procedures governing the adoption of soft law represents a genuine lacuna of EAs' rulemaking. Such lacuna should be filled by the EU legislator when reviewing the establishing regulations, or by the EAs themselves, acting on their own initiative. In the first case, a source of inspiration could be provided by the regulations establishing the ESAs, which envisage the procedures for the adoption of guidelines and recommendations. In the second case, the already recalled EMA's procedural rules could operate as a model for the proceduralisation of other EAs' soft law.[40]

B The Insufficient Development of Consultation

The second issue concerns the content of the emerging procedural framework for EAs' rulemaking. At its current state of elaboration, such procedural framework is explicitly based on two principles of administrative action, transparency and participation, and is centred upon consultation, sometimes complemented by regulatory impact assessment. Is this basic structure coherent with the exigencies of EAs' rulemaking? Or does it require modifications and adjustments?

The main tension concerns consultation. The existing procedural framework may be said to respond to the functional and normative exigencies of EAs' rulemaking in so far as it is based on consultation. At it stands now, though, consultation is insufficiently developed and needs a number of improvements in order to fully exploit its potentialities within the context of the EAs' rulemaking procedures.

Consultation may be considered to respond to the exigencies of EAs' rulemaking for at least three reasons. First, it allows EAs to acquire relevant information and data from private actors. These information and data add to those already available within the EAs themselves through their internal scientific bodies. In this

[39] S. Cassese, 'Il diritto amministrativo europeo presenta caratteri originali?', (2003) 52 *Rivista trimestrale di diritto pubblico* 35, 47.

[40] *supra* § 3.2.

sense, consultation is instrumental to the collection of the knowledge that is necessary to a sound and informed exercise of the administrative action.

Second, consultation is a powerful instrument to stabilise the interactions among regulators and regulatees in polycentric systems such as the networks coordinated by the various EAs, where a multiplicity of regulators and regulatees coexist and interact. Far from being linear and oriented to full cooperation, such interactions may aim at optimising the interests of some parties against those of other parties. The addressees of administrative rulemaking, for example, are not all in the same position: specific groups of regulatees may call for interventions of the regulator to protect their own interests, with the result that formally equal administrative rules may be in practice more convenient for some regulatees than for others. Regulators may reveal a propensity to regulatory intrusion, which might jeopardise the ties between regulator and regulatees within the relevant policy sector. Moreover, they may engage in practices of regulatory competition with other contiguous regulators, especially in overlapping fields such as those managed by the EAs. Consultation, though, is potentially capable of stabilising these dynamics. Indeed, it binds regulators and regulatees to the respect of an argumentative method according to which each party is called to provide the reasons for its own position, the various arguments are to be crossed and discussed in the perspective of identifying and removing possible inconsistencies, and the adopted solution is to be rationally justifiable on the basis of the arguments provided. The argumentative method, in other terms, may contribute to maintain the games of alliances and conflicts typical of rulemaking within the physiology of a polycentric administrative system, by committing each of the parties involved in rulemaking, regulators and regulatees, to the respect of their own institutional position within the process.

Third, consultation permits all interested parties to participate in the process leading to the adoption of administrative rules. In this case, participation is not directly aimed at defending an individual position but at contributing to an inherently 'political' process through deliberation and the exchange of arguments and reasons. Although it may burden the decision-making process and shape it as a corporatist exercise, consultation brings interested parties into the rulemaking process, emphasising its political dimension and importing the participatory model of democratic legitimation within EAs' rulemaking.

In this sense, consultation is a mechanism potentially capable, mainly through deliberation, to contribute both to the rationality and the legitimacy of EAs' rulemaking. As an instrument functionally oriented to provide EAs additional information and to stabilise the interactions among regulators and regulatees, consultation aims at serving the purpose of the quality of EAs' administrative action. As a mechanism promoting better regulation and allowing private actors' participation in the political process of rulemaking, it represents one of the various instruments through which administrative law may enhance the legitimacy of EAs.

At its current state of elaboration, however, consultation is too rudimental and underdeveloped to be capable of effectively serving the purpose of the quality and legitimacy of EAs' rulemaking. Many fundamental details of consultation are missing: this is the case, for example, of the subjects having the power to express their voices in the consultation procedure, of the time of consultation, of the modalities to provide comments on the draft measure. Moreover, the fundamental link between consultation and the duty to give reasons, without which the function of consultation is simply neutralised, is not always formalised. Again, consultation is not always preceded by

impact assessment or cost-benefit analysis at an earlier stage of the rulemaking procedure, such as that of agenda setting. Finally, consultation is never referred to the principle of proportionality, which represents its true legal foundation and should orientate its concrete functioning: by triggering a process of exchange of arguments among the various regulatees and between the regulatees and the regulators, consultation responds to the exigency of committing regulators not only to avoid unnecessarily onerous rulemaking measures, but also to identify the proper intensity and measure of the administrative power.

These shortcomings of the consultation procedure need and deserve to be fixed. This may be done in several ways, such as the adoption of a general legislation on EU administrative rulemaking, the amendment of the various establishing regulations or the development of administrative practices by the EAs themselves.

Whatever institutional channel is chosen, in any case, it should be recalled that the current rules and practices of certain EAs provide a remarkable source of inspiration. The most interesting model is represented by the EASA. As we have already recalled,[41] the establishing regulation requires the EASA to draw on expertise available in the aviation regulatory authorities of Member States, to involve whenever necessary appropriate experts from relevant interested parties, to publish documents and to consult widely with interested parties, 'according to a timetable and a procedure which includes an obligation on the Agency to make a written response to the consultation process.'[42] The main provisions, however, are established by an already mentioned Decision of the EASA Management Board concerning the rulemaking procedure and governing all the various steps of the procedure. This Decision provides an interesting model for the rulemaking of other EAs for several reasons. First, it frames consultation within a wider procedure, whose first step is an impact assessment: the Executive Director is to establish an annual rulemaking programme, supported by a preliminary regulatory impact assessment of each of the rules envisaged and by an analysis of the priority accorded to each task taking into account these preliminary regulatory impact assessments and the resources at the EASA's disposal. Second, the elaboration of the draft measure is regulated with some detail: the Executive Director is responsible for drawing up the 'terms of reference' for each rulemaking task, including a clear definition of the task, a timetable for its completion and the format of the deliverable. Upon completion of the drafting of the proposed rule, the Executive Director has to publish a Notice of Proposed Amendment (NPA) in the EASA's official publication. Third, consultation is regulated in all its main aspects. As for the actors legitimated to participate, consultation is open to 'any person or organisation with an interest in the rule under development.' The consultation period is normally of three months from the date of NPA publication. Most importantly, the decision regulates the crucial phase of the review of comments. The Executive Director has to ensure that comments are reviewed by appropriately qualified experts not directly involved in the drafting of the proposed rule together with the Agency staff or the drafting group tasked with the drafting of the rule in question. A 'comment response document' is then published, providing a summary of comments received and the EASA's responses. If the revised text differs significantly from that circulated at the start of the consultation process, the Executive Director can consider

[41] *supra* § 3.1.
[42] See Art 52, Reg 216/2008.

a further consultation round. In any case, the Executive Director shall issue his/her decision in respect of the rule in question no earlier than two months following the date of publication of the comment response document, in order to allow sufficient time for consultees to respond to its contents.

V Conclusions

The legal inquiry carried out in this article should be taken only as a preliminary step in a complex field of research. It has been essentially based on a bird's-eye view of the EAs' rulemaking, and centred upon EU legislation, implementing measures and soft law documents. It might be integrated by paying analytical attention to the many details of EAs' rulemaking and deepened by a greater attention to law in action, for example through the analysis of a number of case studies.

Despite these shortcomings, the inquiry seems useful in so far as it gives a general account of certain overall orientations of EAs' rulemaking and its proceduralisation. The main conclusions may be summarised as follows.

To begin with, not all EAs are provided with or exercise *de facto* rulemaking powers. Rulemaking activities are carried out by EAs provided with genuinely decision-making administrative powers and by some EAs providing an advisory or technical assistance to European and national institutions. Information agencies, instead, do not seem engaged in any type of rulemaking.

Moreover, two main types of EAs' rulemaking can be identified. EAs may be called to participate, as technical actors, in procedures leading to the adoption of binding implementing rules, either assisting the Commission or directly adopting technical rules. Moreover, EAs are often formally or *de facto* granted the power to issue soft law instruments such as guidance, application guides and communications, either to the regulatees or to the other administrations participating in the sectoral network they coordinate.

Third, most of the procedures followed to issue the measures through which the relevant EAs contribute to the adoption of binding implementing rules are made subject to a rather homogenous set of procedural rules and practices. Such procedural discipline, usually limited to a number of basic provisions, is explicitly based upon the principles of transparency and participation, implemented through consultation, sometimes complemented by regulatory impact assessment.

Fourth, the emerging procedural rules for soft law rulemaking implement the same principles of transparency and participation and rely on the same consultation mechanism, sometimes complemented by regulatory impact assessment. At the current stage of development of EU administrative law, however, one cannot register an overall tendency to formalise the procedures through which EAs adopt soft law measures.

Fifth, the two main types of EAs' rulemaking are not subject to the same degree of proceduralisation. While proceduralisation is consolidated with reference to participation in the adoption of binding implementing rules, there is not evidence of a general tendency to formalise the procedures through which soft law measures are taken, and only a few EAs are called to respect procedural principles and rules for soft law rulemaking.

Finally, far from being a well-accomplished set of principles and rules, the current procedural regimes for EAs' rulemaking present two main shortcomings. One is the unjustified asymmetry between the proceduralisation of the adoption of binding implementing rules and the lack of formalised procedures governing the adoption of

soft law. The other is the too rudimental development of consultation in the existing procedural frameworks, which does not allow consultation to exploit its potentialities within the context of the EAs' rulemaking procedures. Both shortcomings should be tackled by the EU legislator or by the EAs themselves. This is the main challenge for the full development of EAs rulemaking in the next future. What should not be overlooked, though, is that the experience of some EAs already provide best practices and examples to be discussed and considered for possible generalisations and extension to other EAs.

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